IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

THE CITY OF HUNTINGTON,	:	Civil Action
Plaintiff,	:	No. 3:17-cv-01362
v.	:	
AMERISOURCEBERGEN DRUG CORPORATION, et al.,	:	
Defendants.	:	
CABELL COUNTY COMMISSION,	:	Civil Action
Plaintiff,	:	No. 3:17-cv-01665
v.	:	
AMERISOURCEBERGEN DRUG CORPORATION, et al.,	:	
Defendants.	:	

BENCH TRIAL - VOLUME I
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE
UNITED STATES DISTRICT COURT
IN CHARLESTON, WEST VIRGINIA

MAY 3, 2021

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Proceedings recorded by mechanical stenography;
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PROCEEDINGS had before The Honorable David A. Faber, Senior Status Judge, United States District Court, Southern District of West Virginia, in Charleston, West Virginia, on May 3, 2021, at 9:30 a.m., as follows:

THE COURT: The courtroom deputy will please call the case for trial.

COURTROOM DEPUTY CLERK: The case called for trial is the City of Huntington versus AmerisourceBergen Drug Corporation, Cardinal Health, Inc., McKesson Corporation, civil action number 3:17-1362, and Cabell County Commission versus AmerisourceBergen Drug Corporation, Cardinal Health, Inc., McKesson Corporation, civil action 3:17-1665.

Will counsel please note their appearances?

MR. FARRELL: Paul Farrell, Jr. on behalf of the plaintiffs.

MS. KEARSE: Anne Kearse on behalf of the plaintiffs, Your Honor.

MS. CONROY: Mildred Conroy on behalf of the plaintiffs.

MR. MOUGEY: Peter Mougey on plaintiff of the plaintiffs.

MS. SINGER: Linda Singer on behalf of the plaintiffs.

MR. FULLER: Mike Fuller on behalf of the plaintiffs, Your Honor.

MS. ROBERTSON: Pearl Robertson on behalf of plaintiffs.

MR. MAJESTRO: Anthony Majestro on behalf of plaintiffs.

MS. LEYIMU: Tope Leyimu on behalf of plaintiffs.

MR. ACKERMAN: David Ackerman on behalf of the plaintiffs.

MR. WOELFEL: Mike Woelfel on behalf of the plaintiffs.

MS. MAINIGI: Good morning, Your Honor. Enu Mainigi from Williams & Connolly on behalf of Cardinal Health.

Your Honor, I also wanted to introduce Caitlin Anderson from Cardinal Health, who is Vice President and Associate Counsel.

MS. ANDERSON: Good morning, Your Honor.

THE COURT: Good morning.

MR. RUBY: Good morning, Your Honor. Steve Ruby on behalf of Cardinal Health.

MS. WICHT: Good morning, Your Honor, Jennifer Wicht on behalf of Cardinal Health.

MS. HARDIN: Good morning, Your Honor. Ashley Hardin on behalf of Cardinal Health.

MS. SALGADO: Suzanne Salgado on behalf of Cardinal Health.

MR. SCHMIDT: Good morning, Your Honor. Paul Schmidt for McKesson. And I'd also like to introduce our client, Rob Park, from McKesson. We'll have different clients probably mostly in the overflow room throughout the trial.

MR. HESTER: Good morning, Your Honor. Timothy Hester on behalf of McKesson Corporation.

MS. FLAHIVE WU: Good morning. Laura Flahive Wu on behalf of McKesson.

MR. STANNER: Andrew Stanner on behalf of McKesson.

MR. WAKEFIED: Good morning, Your Honor. Jeff Wakefield also appearing on behalf of McKesson.

MR. NICHOLAS: Good morning, Your Honor. I am Bob Nicholas. I represent AmerisourceBergen. Our client is here, as well. Elizabeth Campbell is the company's Deputy General Counsel.

MS. CAMPBELL: Good morning, Your Honor.

THE COURT: Good morning, ma'am.

MR. NICHOLAS: And Chris Casalenuovo as Head of Litigation.

MR. CASALENUOVO: Good morning, Your Honor.

THE COURT: Good morning, sir.

MS. MCCLURE: Good morning, Your Honor. Shannon McClure on behalf of AmerisourceBergen Drug Corporation.

MS. CALLAS: Good morning, Judge Faber. Gretchen Callas on behalf of AmerisourceBergen.

MR. MAHADY: Good morning, Your Honor. Joseph Mahady on behalf of AmerisourceBergen.

THE COURT: Did that get everyone?

The parties having waived their right to a jury trial and consented to trial to the Court, we'll proceed directly this morning to the opening statements and I understand that, Mr. Farrell, you're going to go first on behalf of Cabell County and you may proceed.

MR. FARRELL: West Virginia woke on Sunday, December 18th, 2016, to these headlines. "780 million pills, 1,728 deaths." Eric Eyre from the Charleston Gazette obtained access to a confidential database called ARCOS, A-R-C-O-S, which gave him visibility into the volume of opium pills sold into the State of West Virginia. 780 million pills, enough to hand out 433 opium pills to every man, woman and child in the State of West Virginia.

This headline grabs your attention. It's simple, elegant, and blunt. For his efforts, Eric Eyre won the Pulitzer Prize for investigative journalism. This newspaper series triggered a congressional investigation into pill dumping in West Virginia and has launched what has been described as the most complex and largest litigation in the history of the country.

Despite its complexity, the law of parsimony or Occam's philosophical razor suggests the simplest explanation is usually the right one, Judge. We intend to prove the simple truth that the distributor defendants sold a mountain of opium pills into our community fueling the modern opioid epidemic. The headlines, Judge -- technical difficulty.

THE COURT: First technical glitch of the trial.

(Laughter)

THE COURT: There will be many more, I'm sure.

MR. FARRELL: I don't know where I need to point it. Well, I'm glad I got it out of the way with the very first one.

Gina, do you just want to bring the laptop to me?

UNIDENTIFIED SPEAKER: No. It's --

MR. FARRELL: There we go. The Pulitzer Prize, Judge, in the headlines, "780 million pills, 1,728 deaths." I've circled these two things because this simple, elegant, blunt truth provides the framework for our case, conduct and consequences.

May it please the Court. We have the great honor of representing the peoples of Huntington-Cabell County, West Virginia in this first trial against the distributors of prescription opioids, AmerisourceBergen, Cardinal Health and McKesson, collectively referred to as "The Big Three".

This is a bench trial wherein you serve as both the

judge and the jury. As the judge, you will determine which laws apply. As the jury, you are the finder of fact. You are the audience.

I have told my clients you are a student of history, so perhaps this analogy is apt. Patrick Henry and John Marshall were contemporaries. They were both lawyers. One was known for his power of persuasion, evoking fiery emotion; the other, methodical and convincing. We believe our aim in these proceedings is to follow the path of the latter, to be methodical and convincing.

I believe that we will show you facts upon which you will record in the permanent record as the historian. We will present direct evidence from primary sources, as well as firsthand accounts of what happened here, and seek the truth in this forum. To that noble aim, I take this opportunity to outline our case in chief.

THE COURT: Just a minute. I hate to interrupt you, but second technical glitch. I'm not getting realtime up here. Oh, it's over here. Sorry.

Sorry, Mr. Farrell. Go ahead, please.

MR. FARRELL: It's our intentions during this opening statement to provide an outline of the evidence we intend to present in our case in chief, which will fulfill the elements of proof from public nuisance.

To that end, there are four pillars to our case. The

four pillars are volume. We will introduce in painstaking detail the volume of pills that were sold by The Big Three into Huntington-Cabell County.

The second pillar are what we call black flags. We have an enormous amount of documents and deposition testimony that we have culled into what we believe to be essential facts which will provide notice and foreseeability of the conduct that we will label and walk through with you called black flags.

The third pillar is the morphinan molecule. We're going to have science. In fact, the very first witness you will hear from is Dr. Corey Waller and he's going to walk through why this morphine molecule is so potent, why it is driving the fourth pillar, which is the epidemic.

We intend to outline the four horsemen of the opioid epidemic, addiction, abuse, morbidity and mortality. These four pillars are divided into the theme of our case, conduct and consequences. I'm going to spend the first half of opening, as well as we will spend the first half of the trial, focused on conduct. My colleague, Anne Kearse, will spend the second half of opening, and we will spend the second half of trial, going through the consequences.

So, backing up, before we even start on this journey, we need to remember the lesson from Eric Eyre's newspaper articles. We need transparency. We've demanded

transparency from our clients and ourselves and we've demanded transparency from the defendants.

Through transparency, we can get visibility into the volume and into the conduct. Through transparency, once we establish conduct and consequences, we're going to ask you for accountability. From start to finish. From Alpha to Omega, transparency will lead us to accountability and in between the two are going to be twelve weeks of evidence.

The key to this case is transparency and visibility because, if you can't see the depth of what happened in our community, we can't find the truth, and that will be the process by which we will go through.

Introductions. I'd like to take a few minutes and talk about and introduce our clients and introduce the distributor defendants.

Huntington-Cabell County, West Virginia is in the southwest corner of our state and it sits in the confluence of the Big Sandy and the Ohio River. Huntington is the seat of Cabell County. It's the Tri-State area. You cross the Big Sandy, you find Kentucky. You cross the Ohio, you find the State of Ohio.

Our county has about a hundred thousand people, which is nice because, when we do math for the next three weeks, a hundred thousand is easily divisible. About half of which reside within city limits.

I blow up this particular map because you'll see that the City of Huntington spills outside of the county lines just a bit. And that's important because one of the pharmacies in this case you'll be hearing about, that Cardinal Health in its own internal documents describes as a black hole, is The Medicine Shoppe, and it is in Huntington, but resides within Wayne County.

These are our clients. The West Virginia Code enables the County Commission to represent the peoples of the county and allows municipalities to form governance over those within city limits. Our three Cabell County Commissioners, Kelli Sobonya, Nancy Cartmill and Jim Morgan. Our County Manager, Beth Thompson.

The County Commission has fiscal responsibility over the prosecutor and the sheriff, as well as the County and City Clerk, as well as the EMS. You will hear from and see documents written by each of the three preceding sheriffs, Sheriff Zerkle, Sheriff McComas and Sheriff Wolfe.

The City of Huntington has elected a strong mayor form of government and, Your Honor, we've got one. Steve Williams is here with us today in the audience and he will be testifying in this trial, as well.

The City of Huntington has the Fire Department and the Police Department. Jan Rader will be testifying later this week.

You will see documents in evidence from each of the three preceding Chiefs of Police, Ray Cornwell, Hank Dial and Skip Holbrook. And then, you'll see, I put the city logo of Huntington there because Mayor Williams has had a series of Drug Task Forces where he's been compiling data and we will be bringing in some of that data through the men and women of the City of Huntington.

We are also the home of Marshall University, the proud sons and daughters of Marshall University. In Huntington, we have two primary hospitals, Cabell Huntington Hospital and St. Mary's Medical Center, and I will point out that I have made painstaking detail to make sure that the logos for both hospitals were exactly equal. And it also is filled with the people from our Schools of Pharmacy, The Research Corporation, the School of Medicine, from the Hoops Family Children's Hospital, from our Board of Education, from the men and women who have been deposed, some 80 of which have been deposed in this case. We will be bringing them here and introducing you to some of them.

So, Huntington, West Virginia is a river town. We have a very long and proud history. That history sometimes has included some tragedy.

The Ohio River, in 1937, flooded. The waters of the Ohio River spilled out into downtown Huntington flooding our community, a theme that I'll probably be reaching back to at

several different times throughout this litigation.

We've experienced a new flood. And it's a flood of opium pills into our community. The data that we intend to present to you will establish a mountain of opium pills sold by The Big Three into Cabell County which resulted in the four horsemen of the epidemic.

We will present to you evidence that, in the past ten years, there have been 7,000 overdoses in Huntington-Cabell County and 1,100 opioid-related deaths. In a community of 100,000 people, we have had 7,000 overdoses and 1,100 opioid-related deaths.

So, Huntington-Cabell County has the honor of being one of the very first communities in the country to do something about it, to be resilient. See, we started this litigation here in this courtroom and, in fact, I believe the first status conference was May 2nd, 2017, four years and a day ago.

Soon after Huntington-Cabell County filed the first case, the rest of West Virginia soon followed and, after that, some 3,000 other communities filed, as well, because much like the poppy plant itself, it has a -- this epidemic has a life cycle. If you spread enough seeds, some of those seeds germinate. And, when they germinate, they grow stocks and then they bloom. The opioid epidemic first bloomed in the Appalachia Ohio River Valley and soon communities across

the country saw that blossom, as well.

In this litigation, all of these 3,000 cases were consolidated and sent to Cleveland, Ohio. And in Cleveland, Ohio, a pantheon of American trial lawyers, men and women who I now consider to be my colleagues, rallied to the cause and, for the past three years, we have gone through 37 million documents, some 195 million pages, and taken more than 800 depositions.

So, before we introduce the defendants, I want to take just a brief moment to talk about the chain of distribution. We have in America three primary links for the chain of distribution of opium pills. It starts with the manufacturers.

The manufacturers make the pills, but they don't sell them to the pharmacies. They sell them to the distributors. The distributors then sell them to the pharmacies. It's what Congress has described as a closed system.

We intend to bring a historian to testify this week who will give you some of the background and history of the closed system under the Controlled Substances Act. This closed system has a purpose.

You have to have a registration to be a manufacturer with the federal government. You have to have a registration to be a distributor with the federal government. And you have to have a registration to be a

dispenser as a pharmacy. Not everybody gets the right to sell opium pills in a community without going to prison. You have to have a registration.

I have described it at various times as Willie Wonka's Magic Ticket. If you're one of the few that gets the ticket to sell as a distributor these pills, you got one job. The CSA gives you the job of being the chokepoint. They're not just delivery trucks. They have a function in the closed system.

So, in this case, we started with having lawsuits against the manufacturers, the distributors and the pharmacies. You'll recall, at one time, there were even prescribers that you severed and dismissed on misjoinder, but all of the different facets of the chain of distribution had epically failed and contributed to the opioid epidemic.

We have severed all of the other defendants from this case because there's only one link in the chain that we're focused on and that's The Big Three, AmerisourceBergen, Cardinal Health, and McKesson.

We have spent a tremendous amount of time tracking the number of opium pills that were sold by The Big Three into Huntington-Cabell County. To date, we have been able to track 81 million doses of opium pills attributed The Big Three. 81,239,625 dosage units of oxycodone and hydrocodone sold by The Big Three pursuant to their own data and the

ARCOS data that we've been able to track so far.

The defendants, we've taken depositions of a great many defendants. You'll see on the chart that the defendants have agreed to bring live witnesses. Well, they haven't agreed. It's their right to bring them. We've asked them to bring live witnesses.

AmerisourceBergen is going to bring three from their Regulatory Compliance Program, as well as their sales agent that was responsible for Huntington-Cabell County, West Virginia. Cardinal Health, the same. They'll be bringing two from their regulatory compliance supply chain, as well as the sales agent responsible for Cabell Huntington. And McKesson, the same. They'll bring two from their corporate Regulatory Compliance and their sales agent.

The way we've structured this case is, this week, tomorrow you'll hear science from Dr. Waller, followed by the historian, Dr. Courtright. The next witness will be Dr. Gupta, who will come in. And then, finally, we'll close on Friday with Jan Rader. If we have extra time at the end of the day, we have other data witnesses we may put in.

Next week is the week you're going to love. It's ARCOS week. Peter Mougey, my colleague here and my good friend, is going to go through the math and present to you the ARCOS data. Once he's done, then we're going to begin building the case against The Big Three.

First will be AmerisourceBergen; then Cardinal Health; then McKesson. Now, that's as far as I can see for the next three weeks, but following that, we'll finish up with our experts, and then we'll move into the consequence side of the case.

So now, pulling this all together, our themes, conduct and consequences, none of that matters unless we meet our burden of proof for the elements of proof, conduct and consequences. So, to put this together, we've made this little flow chart. It helps me visualize and see what we're doing.

First thing I want to address is standing. The West Virginia Legislature has bestowed upon the County Commission and the City the power to eliminate hazards to public health and safety. That's what they're doing in this case. They also have the power to abate or cause to be abated anything which the Commission determines to be a public nuisance. They are bringing this on behalf of the public. This is a public nuisance case on behalf of the public.

You'll recall that we've divided between public nuisance and private nuisance in West Virginia. The two governmental entities, the City and the County, have waived their economic losses for their individual private nuisance cases to stand in the shoes of the community they represent and bring this public nuisance case.

We've had spirited debate on what the burden is for the conduct, whether it be unreasonable interference, or negligence, or unlawful, or intentional. Regardless of the level of evidence that rises to these levels, what I'm calling it is actionable conduct.

We're going to show you what we believe to be the duties that The Big Three had when serving as the chokepoint, violations of those duties sufficient enough for you to find actionable conduct. And if we do that, and we establish the consequences, we'll be asking for abatement.

So, one quick note, and I won't spend a lot of time because it's a disputed issue about duty and the Controlled Substances Act, but I do want to reference the fact that we've spent a lot of time thinking about how to take such a complex matter and make it simple.

How do I explain in simple terms what they should have done? And what I found was some inspiration from the design of the morphinan molecule. See, this simple, elegant design of the morphine molecule that is so potent also serves as a guidepost for us to design what we believe to be the obligations of the defendants.

They have to design a system that identifies suspicious orders. Once they identify a suspicious order, they've got to make a decision. They either block it, or they do some due diligence to make sure that diversion is not happening,

and then they ship it. The morphine molecule gives us this simple, elegant algorithm for us to be able to communicate to you what we think the actionable conduct in this case is.

Now, how do we take this story and piece it together in a point where we have a sequence of events that matches all of the data from all of these documents? What I've attempted to do is I've attempted to take a timeline, a timeline that has a sequence of events.

So, over a period of time, we have three defendants who are independently acting at times, at other times working in concert, but in a sequence of events will go back and forth.

How do we show the sequence of events in the context of the volume of pills? That's my goal, Judge. My goal is to be able to take a sequence of events and to show you the timing of the event and the context of the volume of pills that were sold into Huntington, West Virginia.

The first aspect, you'll remember the four pillars. The first pillar, volume. The second pillar, black flags that come from the documents and depositions.

So, we're going to talk about pillar one, volume. The volume comes from ARCOS, A-R-C-O-S. Now, the ARCOS database, this is probably not true, but I envision a huge computer in the basement of the DEA in Virginia. Every transaction that happens between a distributor and a pharmacy is entered in a portal and recorded in a database.

You'll hear testimony from the DEA, as well as references to the DEA's testimony in Congress, that this data historically was not used on a pro-active basis. And what I mean by this is that just like the stock market has billions of transactions that happen every day, the fact that the transaction goes through doesn't mean it's a clearinghouse.

You don't get a free pass safe harbor because your transaction went through. The SCC can look backwards in time and recreate what happened. So, the DEA has testified that they used the ARCOS data to look backwards in time to build on investigations, but not until recently were they using it on a pro-active basis to look for trends.

This is a data chart from the national ARCOS data. See, the ARCOS data is confidential. Before Eric Eyre got access to it, it had never been in the public domain. The only thing that had ever been in the public domain was the DEA would publish summaries. And those summaries, you could look at national trends.

This is a summary from the DEA that shows from '97 to 2019 the volume by weight of what was sold by all distributors in the country of hydrocodone and oxycodone, the oxycodone being in blue; the hydrocodone in orange.

This data, you can also break out by state. We're able to take the state data published by the -- by the DEA, the

summaries, and be able to see the volume by weight of the pills, the active ingredient weight of the pills, into West Virginia during the same time frame. Again, this is all sellers, all distributors into the United States and into West Virginia. And, of course, the scale is different, but the pattern is the same.

What we're able to do is we're able to take some of this ARCOS data and make measurements. This is the oxycodone and hydrocodone shipments to retail and chain pharmacies. No hospitals, no VAs, no nursing homes. This is pharmacy dispensing. The ARCOS data tells us that West Virginia was getting more doses per capita than any other state in the country.

Now, you may say, well, what if these pills are just the small ones, the little 5 milligrams versus the 30 milligrams? Well, we can also measure it by weight. This is the weight, the active ingredient of the drug. By weight, West Virginia has the highest weight per capita in the United States.

You can compare states to states. This is West Virginia, for Cardinal Health, sold 130 million. To the State of Illinois, they sold only 80 million. AmerisourceBergen, 66 million in West Virginia, 60 million in Illinois. McKesson, 116 million to West Virginia. 78 million to Illinois.

You can also stack states. This is Cardinal Health's sales by state. Nebraska, 22 million; Iowa, 25 million; Illinois, 77 million; Texas, 79 million. In West Virginia, they sold 130 million.

Now, from the summaries the DEA provides, publicly available, we're also able to take and look at a more narrow section than the state. So, like a powerful microscope, we can look at the national. We can look at the state. But the DEA summaries only stop at three-digit zip code.

So, you can see that Huntington and Cabell County fall within two zip codes, 257 and 255, and you can see that 255 extends down to Wayne County up to Point Pleasant in Mason County, over to Teays Valley in Putnam County a little bit, and it looks like it even gets down into Chapmanville and Madison, way down in Boone, Logan, Mingo areas. These are the two zip codes that the public has access to and visibility.

So, what we're able to do is, we're able to take a look at patterns of sales in the United States, between the United States and West Virginia, 255 and 257, and then combine 255 and 257.

So, what I intend to do is I intend to use as a rubric for opening the 225-257 chart to walk through the context of the black flags knowing, as a spoiler alert, that we can do the same on any level that we want now that we have the full

ARCOS data.

Judge, I'm going to do my best to bring up the white board without -- I know I'm blocking counsel, if they want to go to the jury box or move their seats.

THE COURT: Yes. If you need to see, you can move.

MR. FARRELL: Judge, can you see the board or do you want me to bring it closer?

THE COURT: I can see it where it is, if that's where you want to put it.

MR. FARRELL: I'm going to be drawing on it, too.

THE COURT: Okay. We'll see where we go, Mr. Farrell.

MR. SCHMIDT: Your Honor, could we sit here or go to the jury box?

THE COURT: You can go anywhere you can see, Mr. Schmidt.

MR. SCHMIDT: Thank you, Your Honor.

MR. FARRELL: So, for orientation purposes, right? So, in general, what you can see from these charts, all sellers. That includes more than just The Big Three. This is what we see from the summaries of the DEA. It only gets focused down to the three-digit zip codes.

Now, what it also does is it breaks up the pills by base code. What I mean by that is that the DEA summaries

differentiate between oxycodone and hydrocodone, but it only tells us the weight by milligram. What we'll also be looking for is dosage unit, DU, and morphine milligram equivalent. You'll be hearing MME.

So, this is my segue. This is my trigger slide to stop for a second and talk about MMEs.

We're going to call the first witness, Dr. Corey Waller, and he's a smart fellow that knows all about the molecules. He's going to come in and tell us why this particular molecule has resulted in the potency that we're seeing. You see, the morphine molecule has a structure, a base structure, that is the same core structure to hydrocodone, oxycodone and heroin.

He's also going to explain why the synthetic molecule Fentanyl, it's synthetic manmade, has the same impact on the brain. Dr. Corey Waller is going to show us the family of molecules. He's going to talk about the potency and how each of these molecules engage the brain in a different, more lethal, potent way, describing the difference between hydrocodone and oxycodone.

Using MME as the baseline, hydrocodone is an MME of 1. That means 1 milligram of hydrocodone is equal to 1 milligram of morphine. Oxycodone has an MME of 1.5. What that means is, is that for every one milligram of morphine, oxycodone is a 1.5 of that.

So, by way of example, if you have a 10-milligram hydrocodone pill, its MME is 10. If you have a 10-milligram oxycodone pill, it has an MME of 15. Hydromorphone is 5:1. Fentanyl can be up to 100:1.

So, Dr. Corey Waller is going to come in and he's going to show us the molecules. And then, what he's going to do is, he's going to take these molecules and he's going to show us how they are all the same core structures. And then we're going to tease them back apart. This is why the relationship through science between prescription opioids and heroin is a proven truth.

So, in summary, looking at this board, yearly summaries of all sellers to all buyers by three-digit zip code, base code, and by weight, we're going to use this as a rubric.

Now, Judge, what we've done in this case, and what you're going to hear in painstaking detail, is that we got access to the transactional data from each of the three defendants. We got access to the data they provided to the DEA. We combined it, and we stuck it, and processed it into a large database, so then it's now searchable and index-able.

We can sort it however we want. If you fill the Metrodome filled with pills, some of them are yellow, some are blue, some are 10s, some are 30s, some are shaped differently. You can just dump them all in. We have

basically geotagged each shipment so that you can pull out using math and figure out how many pills were shipped by a defendant to a pharmacy on the second Tuesday of odd years.

We've done our math in every which way we possibly can and we're going to demonstrate that math to you until, at some point, you say, no mas, I get it. I understand you've done the math. That's our goal. That's our mission.

We're going to be able to show you not only the charts from a two-digit zip code, we're also going to blow it out and show you the charts by defendant. We're also going to pull out not by defendant, but by pharmacy. We call it top down and bottom up. We can show you from the top down averages and regionals or from the bottom at the pharmacy level up.

This is a list of the ARCOS orders and reporting in the -- in the Federal Register, as well as the Sixth Circuit on ARCOS. We've got a large book here that we're going to be able to walk through the foundation to ARCOS because, you'll remember, on May 2nd, 2017, when I was here, I did not have as big of an entourage, but what I asked for, if you'll recall, is I asked you to allow me to release the hounds because I wanted to serve a subpoena on the DEA and you told me to be patient.

We were patient. When it was our time and our turn, we served a subpoena on the DEA. We have an enormous

litigation book to walk through the foundation of where this data comes from, how we got it, and what we did to it.

So, now that we've taken the black and white and turned some color into it with the -- with some focus, now I get to the next aspect of my challenge, right? I can show context over time. How do I show the actual conduct over time? I can show volume over time. How do I show the black flags over time?

We've basically taken the documents and we've divided it into four barrels. What the -- what the defendants said to the DEA, their communications with the DEA, their communications with Department of Justice and the DEA when they entered into settlement agreements, their testimony before Congress, and what they've said in judicial proceedings.

Now, there's four more barrels. Those four barrels are what they said internally at AmerisourceBergen, what they said internally at Cardinal Health, what they said internally at McKesson. And then, this is HDA. This is the documents from their trade group where we're going to establish at various times this worked in concert with each other.

We're going to pull from all eight buckets the relevant key facts and we're going to stick it in a new barrel that I'm calling the black flags.

First black flag -- well, before we get to the first black flag, reference point. I've made this cute little OxyContin rocket ship and I'm going it put it right here on '96 as a reference point. This is the launch of OxyContin, approved in '96, hit the market, and you can see in '96 where the beginning is of the story.

The first black flag. It's going to be Document P-28207. This is the hearing in 2001 on OxyContin, its use and abuse. The reason that I'm calling this a black flag is when you look at it on the chart, and you can see why this hearing was called, between the launch of OxyContin and in 2001, something happened in America to the point where Congress called for a hearing.

And this is the famous turn of words from the Congressional Report. "The use and abuse of Oxycontin provides quite a dilemma for us in Congress and for the American public. For some, OxyContin is the Angel of Mercy. For others, it is the Angel of Death. To those who suffer severe chronic pain, it brings welcome relief. For those who abuse this highly addictive drug, it can be bring even greater suffering."

This is important not for the truth of the matter. This is notice.

I'm going to break every rule on PowerPoint presentations by making this one busy, but I'd like to read

it because this is notice and foreseeability that between the launch of OxyContin in 2001, something was happening in America. Since this is a new problem, allow me to give the Committee a little background on what OxyContin is and why its abuse has such devastating effects. OxyContin is a high potency painkiller derived from opium. When used as prescribed, it provides effective pain management for cancer patients and others suffering from chronic pain. When properly taken, an Oxycontin tablet is time released and provides the patient with up to 12 hours of pain relief.

The danger arises when that time release mechanism is bypassed. Abusers will either chew or crush a tablet, so that it can be snorted or mixed with water and injected like heroin. This puts the drug into the system all at once and delivers an intense high, much like high grade heroin.

This is why OxyContin is sometimes referred to on the street as "Poor Man's Heroin" or "Hillbilly Heroin". Notice and foreseeability.

This is from a prosecutor that testified. "My biggest concern as a prosecutor and someone in public health is the potential that it is truly a gateway drug to more serious abuse and, specifically, heroin. And when we begin to deal with somebody who is addicted to heroin, we have significant issues, both from a public health perspective and a law enforcement perspective, because of the associated crime

that often is associated with the necessity, to find the money to pay for it."

Regardless of whether this is true or not, this has been in the public notice and debated since 2001. This is from Purdue himself. Not Mr. Purdue, but from one of the Purdue guys. "When we launched OxyContin, we saw very little evidence of abuse and diversion until sometime around 2000, which, based on the testimony I've heard from other panelists of that time, that type of abuse and diversion was noticed. Black flag number one.

2001, OxyContin is launched and it is doing something in America. Notice and foreseeability. Black flag numbers 2, 3 and 4.

The DEA was charged by Congress to do something about it. They held distributor initiative meetings. It's P-9112, P-9114, and P-12805. These are all in 2005.

So, you can see in the interim, something else is going on, right? It's not -- the flood waters are not abating. They're going up. So, the DEA scheduled meetings with every distributor in the country. They went and had these meetings and they documented and described what they did.

And what you'll see is that they even included a PowerPoint presentation. In 2000 -- and we have the decs produced in discovery from each of the defendants. The power -- the PowerPoint presentations include a discussion

about their obligations, notice of their obligations in 2005 of what a suspicious order is according to the DEA, and what their duties are according to the DEA.

They identified for them issues to consider, including looking at the percent of controlled versus non-controlled. They told them that this isn't just limited to the internet pharmacies. This is your duty according to the DEA.

In addition, they referenced a 1943 case. This is in the PowerPoint slide and, Judge, they actually gave the case to the defendants. We know this because it's in their files.

And I'm going to take a minute to talk about this case because it's a message. It's notice, it's foreseeability, and it's accountability, all three.

In 1943, a wholesaler was selling morphine sulfate to a doctor in North Carolina. The doctor was then selling it to patients that were addicts. The addicts were arrested, indicted and convicted; the doctor, arrested, indicted and convicted.

And then, the federal government arrested, indicted and convicted the wholesaler. The defendant wholesaler took this case all the way to the United States Supreme Court and raised, spoiler alert, a defense that their only job was to make sure that the person they were selling to had a stamp book pursuant to the Harrison Narcotic Act.

They said that as long as the doctors got a stamp, I can sell them the pill. You can't hold me responsible for something that happens so far down the stream.

The United States Supreme Court had something to say about that. It said, "The difference between sugar, cans -- sugar, cans and other normal trade, on one hand, and narcotic drugs, machine guns and restricted commodities on the other, arise from the latter's inherent capacity for harm. The United States Supreme Court said narcotic drugs have an inherent capacity for harm and that from the very fact they are restricted makes a difference in the level of proof required to show knowledge that the buyer is going to do something bad with it.

Additional facts, such as how much, the quantity of sales, high pressure sales methods, abnormal increases in the buyer's purchases, which would be wholly innocuous when you're talking about sugar, may furnish conclusive evidence, in respect to restricted articles. Conclusive evidence that the seller knows the buyer has an illegal object and enterprise. Knowledge, on the one hand, may be equivocal; on the other, becomes more secure.

The United States Supreme Court said that the wholesaler selling that much morphine to this doctor, the primary effect was to create a black market for dope and increase illegal demand consumption. When the evidence

discloses such a system, working prolonged cooperation with a physician's unlawful purpose to supply him with his stock and trade for his illicit enterprise, there is no legal obstacle to finding that the supplier, the wholesaler, not only knows and acquiesces, but joins both mind and hand with him to make its accomplishment possible.

The message from the DEA by giving them this case is that you'll be held accountable by selling narcotics.

Now, an interesting follow-up note to the distributor initiative meeting. All three of them, AmerisourceBergen, Cardinal Health, McKesson, happens in 2005. In early 2006, the DEA circles back because McKesson, in the document, is having trouble seeing the problems the DEA is talking about and, as confirmed in the internal documents of the DEA and from McKesson, they document that one of the reasons they were not able to see the full volume of hydrocodone product going out to the Florida pharmacies was their reports only included the brand. They weren't even watching the generics.

As a result, what happened is, is that Joe Rannazzisi from the DEA, after these meetings, Joe Rannazzisi sent out a Dear Registrant letter to every wholesaler in the country. We're going to introduce not only -- not only are we going to introduce Joe Rannazzisi's letters, but we're also going to introduce his 2006 -- or his -- his testimony. Mr.

Rannazzisi is going to come to trial and he's going to tell you that this letter that was sent out followed up on his distributor initiative meetings on what he was seeing in 2005.

The purpose of the letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces. Distributors are, of course, one of the key components to the distribution chain. If the closed system is to function properly as Congress envisioned, distributors must be vigilant in deciding whether prospective customers can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical. 2006, notice and foreseeability.

The next black flag, AmerisourceBergen. AmerisourceBergen gets an immediate suspension order and, within two months, they entered into an agreement with the DEA. Now, this agreement has no admission of liability and no monetary penalty, but they're sanctioned on their reporting.

But this is important. After being told to do better, they promised in this agreement that they will maintain a compliance program designed to detect and prevent diversion.

June 22nd, 2007, the next black flag. Now, this is a letter from the discovery that was previously confidential.

It's from AmerisourceBergen to the DEA about the execution of the protocol following that first settlement and, in it, McKesson tells the DEA any orders which the local distribution center cannot confirm as legitimate are to be held and not shipped to the customers pending more in-depth inquiry by AmerisourceBergen's National CSRA Investigatory Group. National. They say that it's going to go through Mr. Zimmerman, the Vice President. He'll be here to testify. He's the first one we're calling.

The next black flag. Following ABCs' -- ABDC's Settlement Agreement, other inspection warrants had been going out, other immediate suspension orders. Joe Rannazzisi sends a second letter to every registrant in the country. And this is in December of 2007.

And, in this, he says, "To avoid any confusion, registrants that routinely report suspicious orders, yet fill these orders without first determining the order is not being diverted into other than legitimate medical scientific and industrial channels may be failing to maintain effective controls."

This is McKesson's settlement. This is 2008, the next black flag, P-10. This is May 2nd, 2008. McKesson gets an immediate suspension order. The DEA tells them, do better. They entered into a Settlement Agreement and, again, no admission of liability, but what they do is they also tell

them, we'll do better, DEA. We will maintain a compliance program designed to detect and prevent diversion. And they paid a fine of $13,250,000.00.

The next black flag, P-70. This is September 26, 2008. This is Cardinal Health's settlement, settlement number one. And in this, again, Cardinal Health, no admission of liability. They were told to do better and they promised to do so. They promised to maintain a compliance program designed to detect and prevent diversion. Here we are on Pill Mountain. They paid a fine of $34 million dollars.

Now, this is where the story begins to shift. So, when we're looking at our story board here, OxyContin launches. There is a substantial increase when Congress holds its hearing and the DEA is coming and giving black flag warnings while these pills continue to rise.

And then, what happens in October of 2011 begins to change this story. The DEA issued a warrant for inspection to the same facility that Cardinal Health had their first Settlement Agreement with in Lakeland, Florida. Cardinal Health wrote a letter to the DEA after they got that. Now, remember, they paid -- they had their first settlement. They've been warned and warned. They've entered into a Settlement Agreement.

And then, what happens is, is the DEA shows up with seven investigators and executes a warrant for inspection

and, the next day, Cardinal Health's Chief Counsel writes a letter to the DEA. It's P-16706. You'll notice I grab documents in a hope of some visual cue that this is important.

On Page 2, General Counsel says to the DEA, we notice you came in yesterday with seven people on the same facility you did a year ago. Two years ago. This is a quote. "We are acutely aware of the need to closely monitor pharmacies who order large amounts of controlled substances, particularly substances that are frequently diverted and misused."

Because Cardinal Health recognizes the serious harms that are caused by the diversion and abuse of controlled substances, we're asking for your cooperation to help us find those that are diverting it. Notice, foreseeability, acknowledgment.

Then this happens. The DEA issues a rule to show cause and immediate suspension order on February 2nd, 2012. So, whatever happened between October and February after the inspection warrant, the DEA goes and now, for the second time, hits Cardinal Health. And the reason is because, when they looked at the records, Cardinal Health paid a $34 million dollar fine back in 2008 because of the conduct of its top four pharmacies.

The DEA went back to the same facility and when they

looked at the following year, Cardinal's top four pharmacies had an 803 percent increase. The next year, on top of that, 162 percent increase.

So, following this timeline, my colleague and good friend, Jayne Conroy, calls this my popsicle slide. What we see here is we see a dividing line of conduct. The DEA comes in and says in Rannazzisi letters, do better. They come in and they issue an inspection warrant and an immediate cause order to AmerisourceBergen. And then, AmerisourceBergen comes back and says we promise we'll do better.

The second Rannazzisi letter. And then, McKesson gets one. And an immediate suspension order. Do better. McKesson comes back and says we promise we'll do better.

Cardinal Health comes in. Do better. They say we promise we'll do better.

And then what happens is, is that the second time around, the inspection warrant goes out, Cardinal Health says, hey, we're trying. And then here, the second show cause comes out. Second one. And the reason it's different is because when the DEA came back here and said do better, the tone changed. Instead, what they did on the very next day is they filed a dec action, a TRO, and requested a preliminary injunction in the *Cardinal Health v. Holder* case in the District Court of Columbia. Now, not the DC Circuit

Court. This is the District Court of Columbia.

The other interesting thing, Judge, is what happens here is that not only does Cardinal Health fight back, they have help. The yellow triangle is the trade group, HDMA, who files an amicus brief. Now, I know you're going to ask what evidence do you have that these defendants were participating in the amicus brief. We've got the entire build-out. We're going to be able to somehow that not only is this supported by HDMA and voted on and validated by the Executive Committee, but all three sit on the Executive Committee and the minutes show that they approved it and, in fact, despite the amicus brief's footnote that no other party reviewed or edited the document, we have internal documents that Cardinal Health actually provided input on the amicus brief.

So, what changed? These are the defenses that were raised. We have both the administrative record and the Cardinal Health record, right? What you're going to see is that the defenses that are raised in this case were first raised back in 2012. And not only were they raised by Cardinal Health, and in the amicus brief, but what you're going to see is this block here. This block is going to be the defendants acting in concert asserting their defenses and fighting back. The empire striking back.

This is no longer do better. We will. Do better. We

promise. Do better. We promise. Do better. We promise. Do better. We didn't do anything wrong.

So, the next thing that happens after the TRO is briefed and argued and the amicus brief is submitted, the *Cardinal Health v. Holder* case actually comes out. And in that case -- I happen to have a copy of it here in my hand.

The TRO was initially granted, the preliminary hearing happened on March 7th, and it was denied. Soon afterwards, what happened? Cardinal Health enters into the second Settlement Agreement. This time, they acknowledge wrongdoing and pay another $34 million dollar fine.

What happens next? A little case called *Masters*. The DEA goes and yanks Masters Pharmaceutical's license. Now, think about it. They were paying fines, paying fines, promising to do better. The second time around, they react differently, and they're now reacting to license revocations. No longer just worried about fines, a license revocation.

And in the *Masters* case, the HDMA, in concert with and in documents we'll provide to you, took a position fighting the DEA validated and endorsed by AmerisourceBergen, McKesson and Cardinal Health.

The next thing that happens, McKesson gets hit for a second time. This time, McKesson accepts responsibility and they pay $150 million dollar fine. The DEA press releases

call it the largest fine in the history of the DEA.

What happens next? Well, Judge, what happens next is we were here in this courtroom on June 20th, 2017. So, at this time, we -- we -- we didn't know all of this back history, right? On June 20th, 2017, I think I sat at that desk this time. And over here were the defendants. And the defendants stood up here on June 20th, 2017, and they repeated the same defenses. They said they had no duty to block shipping.

Ten days later, the *Masters* case comes out. Ten days later, after that argument, the *Masters* case came out and it provided another validation of the DEA's position. For the *Masters* case, what is important is what you'll read, is that the -- the DC Circuit Court addressed some of these defenses. The same defenses.

What happened next? We went to Cleveland in the MDL and, in the MDL, we filed what we call SOMSA based on *Masters*. The defendants opposed it. And what happened is they lost there again.

What happened next? CT-4, San Francisco. Again, the defendants raised the same defenses. In San Francisco, Judge Breyer rejected it. And then, in summary judgment, we asked for SOMSA here and the defendants are still denying it.

Something changed. Something made this shift from one

-- at 2012, from one of do better. We promise. To do better. We didn't do anything wrong.

So, what changed? That's for argument at closing. We will be presenting evidence on a couple of things. We're going to be presenting evidence that the second round of DEA immediate suspension orders carried a heftier weight of revocation.

We're going to present evidence that, at this same time frame, this shift, the West Virginia Attorney General filed his first lawsuit against the distributors, a first in the country.

And as my colleague, Anne Kearse, is going to show, what also happened is the rising fatal overdoses were grabbing headlines across the country.

So, I'm going to plug this into the NWDA, HDMA, HDA. This is the trade group. Dr. Courtright is going to have an interesting fact for you. The 1914 Harrison Narcotic Act, there's actually testimony from back then by the same trade group. Back then, they were called the NWDA. It's actually pretty interesting.

They then changed to HDMA. And then, more recently, the HDA. So, you're going to see documents that we present from the trade group. Some of them are NWDA, some of them are HDMA, and others are HDA, but they're all the same.

This is what I think from what we could track is the

tipping point. These are the minutes from the HDMA meeting. And you'll see present are AmerisourceBergen, McKesson and Cardinal.

April 6, 2012. They discuss the *Cardinal Health/Holder* action. And in a quote that -- I was going to say something cute, but in a direct quote, they talk about they're going to review events and plot a course going forward. I couldn't have picked a better word, plot a course going forward.

The course they went forward, Judge, is to embark on a media campaign. These three companies funded -- sitting on the Executive Committee -- funded and directed a media campaign beginning in 2012. One of the things they did was they did focus groups, including here in West Virginia, and one of the assessments is this. Without access to data, respondents question how distributors can be held responsible.

And now, I'm thinking back to May 2nd, when I asked to release the hounds and no one wanted to. And now, I think of when we get to Cleveland and we fight so hard to get the ARCOS data. Their own research indicates why they don't want the data. Why they don't want visibility.

They actually made a crisis playbook. This is literally -- P-38. This is a crisis playbook designed by the trade group circulated amongst the defendants. We'll

show you the bill. We'll show you the foundation. We'll put it in their hands for comment.

They go through scenarios, Judge. They go through what happens if the DEA tries to suspend you. Now, this is what -- this is what I want to point out, Judge. Scenario 1, crisis playbook. What happens if the DEA registration suspension? And do you know what their advice is? This is what they say. Does this present an opportunity for HDMA to proactively push its message of mis-directed DEA enforcement with national media?

Now, let's take a look at this. This is 2012. We're talking here. Does this provide an opportunity for us to proactively push a message of mis-directed DEA enforcement with national media?

They also predict diversion lawsuits. They say what are the facts surrounding the distribution to the alleged pill mills? This is -- this is notice. This is 2012 acknowledgment, hey, we got -- we got an issue here. We may have crises.

They predict a Congressional inquiry. They go through the key considerations of what happens if this turns into us going to Congress? Guess what? They went to Congress. Congress published a huge report.

Do you know how I know they went to Congress? I'm going to get in trouble by my wife for saying this because

she told me not to. It's because that's my bald head right there (indicating).

What else did they do? And this is unbelievable. Turning the tide in West Virginia. Not turning the tide of overdoses. Not turning the tide of pills. Turning the tide in West Virginia.

This is what they said. And I hope my friend Eric Eyre is here somewhere listening to this. During the past three years, a state lawsuit against healthcare distributors has put the blame of pain-killer abuse squarely on the shoulders of healthcare distributors. It asserts that these companies flooded the state with more than 200 million pain-killers over a 4- to 5-year period which, in turn, fueled the rampant prescription drug abuse problem in the state. Yet, the reality is a far cry from the imbalanced picture painted by reporters, particularly Eric Eyre of the Charleston Gazette. This is 2015. He wouldn't win the Pulitzer for another two years.

They talk about the situation, 2015, the pills, the data. That's the situation. What's at stake? Not lives. The credibility and reputation of our industry. More litigation. The passage of a Marino bill where they're attempting to take away the ability of the DEA to revoke licenses without going through another procedural process and give them an opportunity to cure it.

Keys to success. They've got to re-frame the issue. Tell the rest of the story. Take bold steps. Inoculate the industry against future flare-ups.

Key messages. Now, these key messages in 2015, this is -- probably needs a footnote. This needs a footnote to 1943 and it needs a footnote to *Cardinal Health v. Holder*. They should have attributed it to these defenses and key messages.

So, here we have it. Before 2012. Do better. We promise. After 2012, second time around, do better. You can't make us.

So, I'm going to circle into this now in a little more detail, just so you know that we can be painful about it. This is what AmerisourceBergen sold to a pharmacy in Huntington, West Virginia. This is Safescript. This is the state average in green. This is the national average in orange. You'll see the precipitous drop-off. It's when the DEA shut them down.

500,000 oxycodone and 250,000 hydrocodones in 2006 to this pharmacy on the west end of Huntington. This is from their internal documents.

Erik Martin, he's in charge of Ed Hazusky (phonetic). The customer has been adjusted, meaning we've bumped their thresholds. It is now set at the maximum they can receive this product -- by the way, their controlled substance ratio

is 86 percent of the overall purchases. What that means is, is that 86 percent of the pills they buy from us are controlled substances.

Erik Martin, the guy in charge, this is his motto. See everything. Overlook a great deal. Correct a little. Whether it's a pun or not, he's quoting Pope John XXIII's managerial style. The guy in charge of watching out for our community uses as a tag line on his signature block. See everything. Overlook a great deal. Correct a little. What he was overlooking was what happened in Huntington-Cabell County, West Virginia.

Now, this is the last major point on conduct. Judge, these systems, these -- these systems that they have, they have multiple distribution centers, more than twenty around the country. These systems they're required to design are not isolated. What happened in Cabell Huntington is not isolated.

We intend to prove that their systems were nationwide and systemic. And we intend to prove and show you that there was -- successes were nationwide and systemic and their failures were nationwide and systemic.

This is a chart that we will provide to you. The first three columns is our attempt by defendant to break down the national average, the state average, and the average pills to pharmacies in Cabell County.

The next middle column are the actual pharmacies that they sold to in Cabell County.

And then, the final column are the different pharmacies from around Southern West Virginia in the region. And we are going to put this in because we're going to establish that their failures were systemic and nationwide.

The volume of pills that was going to -- to Safescript, that's not the anomaly. There are shipments in the hundreds of thousands per month. This is -- this is -- where's the McKesson one?

This is McKesson's chart. And we've got a flat one, so I'm hoping you put it out on your -- on your table and you cross examine us on it, and you hold us to it, and you say you'd better prove it.

Look, this is -- this is from McKesson. They're selling 179,000 pills a month to a pharmacy in Logan County. They're selling 200,000 pills to Mingo County.

You look at the numbers. This isn't an isolated event. This is documented pills coming in in truckloads to communities across West Virginia and in Cabell County.

Now, I'm going to move through this quickly. I'm almost done, Your Honor. I know. I see you looking.

THE COURT: You've got about ten minutes.

MR. FARRELL: Yes, sir. I'll be done in -- I'll be done in ten minutes.

THE COURT: Okay.

MR. FARRELL: Oxford English Dictionary, diversion. It seems to me that one of the big fights in this case is going to be between liability and damages; causation, right? We're going to spend a lot of time on causation because, you see, there is no tracker on pills in the black market. There's no inventory of pills in a black market. That's because these pills have been diverted.

The definition of diversion, I looked it up, an instance of turning something aside from its course. An activity that diverts the mind from something tedious or serious concerns. As a verb, to cause to change course or turn from one direction to another. And this is my favorite. Diversion, and we're going to be talking about pills being diverted, but diversion, drawing attention away from something. Right?

The attention in this case we're going to focus on is more likely the OIG's definition in 2002. Diversion occurs when legally produced and controlled pharmaceuticals are illegally obtained, right?

We're going to show you diversion through the Congressional history and the DSA. We're going to show you diversion through the Rannazzisi letters. We're going to show you the testimony from the DEA itself that goes through five questions that establish the causal links.

We're going to go and show you that they even made parodies about diversion, right? They made parodies about pillbillies in West Virginia. They circulated amongst the people responsible for oversight of Huntington-Cabell County. They made a pillbillies parody. Right? We're going to go through their actual manuals.

I will show you -- we will show their actual prescription drug diversion training manuals. We'll go through one for AmerisourceBergen. We'll go through one from Cardinal Health. And then, we're even going to bring out one from Gary Boggs, who was former DEA, now works for McKesson. We're going to show you his PowerPoint presentation that he gave to McKesson, right, and in this, what he does is, he talks about history.

Well, that's how we're starting tomorrow. We're going to bring in an historian. Talks about a collision course of Oxycontin and Percocets. He talks about the rising rates of opioid. Talks about the Controlled Substances Act. He cites the statute.

He says what happens when the closed system collapses? A disaster. He talks about the explosion of pain clinics affecting the entire East Coast. They even make a historical perspective of the $40 billion dollar fine arising out of the explosion, 200 million gallons of crude oil spill. The coastline, right?

He's even talking -- he's making comparisons to the impact. He even makes reference to oxy spill, The Blue Highway.

And I'm not going to bore you with it all now, but it's just -- the slides are going to show that with great power comes great responsibility and they blew it.

So, finally, what we're going to do is, we're going to return back to transparency and accountability, right? Transparency through the conduct. And we'll get to the consequences.

My colleague, Anne Kearse, is going to come up and she's going to spend time talking about the four horsemen of the public health epidemic, talk about public safety and, in general, Judge, I'm here to tell you, we have a plan. Thank you for your time.

THE COURT: Thank you. Let's come back at ten after the hour and we'll try to get -- that will give us almost 15 minutes. We'll be in recess until then.

(Recess taken)

MR. SCHMIDT: Your Honor, Paul Schmidt from McKesson. I should have said this at the beginning. I apologize for jumping in. We don't -- it's not our practice to interrupt with objections during openings, particularly in a bench trial. I assume Your Honor is fine with that and that we can just reserve our objections for when some of

this evidence comes in.

THE COURT: Yeah, sure.

MR. SCHMIDT: Thank you, Your Honor.

THE COURT: Yeah, there's no reason in a bench trial to worry about the objections. You can make them later and I'll try to sort them out.

MR. SCHMIDT: Thank you, Your Honor.

THE COURT: Ms. Kearse, are you ready to go?

MS. KEARSE: Yes, Your Honor.

Good morning, Your Honor.

THE COURT: Good morning.

MS. KEARSE: We had some introductions this morning. I'm Ann Kearse with the City of Huntington, but we also have for this afternoon, the second part, Rusty Webb who is also my counsel for the City of Huntington. I'm not sure if anyone else has come in or not.

THE COURT: Mr. Webb is a bit known to me, Ms. Kearse.

MS. KEARSE: We wanted to make sure you knew he was here.

THE COURT: I wouldn't have recognized him with the mask on but --

MS. KEARSE: Your Honor, this case is about a city, a county, and a community. You heard today Mr. Farrell talking about the promises that were made and the

promises that were broken. I'm going to tell you today about what those broken promises did to our community.

This case is about the unreasonable interference. It's about the unreasonable interference with the public health, public safety, and the public peace of this community.

The City of Huntington and Cabell County have been ravaged by the opioid epidemic. Despite their best efforts, this community needs help in dealing with this crisis.

You will hear from this community about the continuous battle with opioid addiction and the resulting epidemic of drug use and related harms.

Mr. Farrell told you today how we're going to proceed through this trial. Transparency was at the top, and then the actionable conduct Mr. Farrell talked about this morning. I'm going to spend this opening section on the community harm and the consequences of that actionable conduct, and the remedy and the recovery we'll ask Your Honor to consider in order to help this community.

Today this community comes before this Court and brings their case within the bounds of the law to tell their story.

I mentioned this case is about the public health, the public safety, and the public peace of those communities, rights that they have to be able to move forward and take care of their communities.

This case is about a community that came to understand

that the health crisis they now deal with is a dual problem. A fire was lit by the oversupply of prescription opioids and pills coming into their community and fueled by the illicit drugs, including heroin and fentanyl.

This community did not shy away from this crisis. They have been transparent. They have sought answers. Rather than be defined by the epidemic, they've acknowledged it and addressed it, Your Honor.

They are in the midst of an opioid epidemic and opioid addiction epidemic. They say the first thing with addressing addiction is to admitting you have a problem. That's what Cabell-Huntington has done.

They sought to change the perception of opioid addiction from a moral failure to one of a medical issue where recovery is possible. People were listening. People were watching. And they became known as the epicenter of the epidemic, of the opioid epidemic.

This community has continually openly addressed the issues they face. And, Your Honor, this is important when we say what this epidemic has done to the community. They couldn't get away with it. But Mayor Williams, who's here today, will testify in this trial openly talked to the state and the city, addressed it to their citizens. In 2015, "The single largest issue we are facing is the level of addiction in our community."

In 2016, "The opiate epidemic that is so devastating to the fabric of our community, our families, our neighborhood is being wrestled to the ground by several fronts. Rather than be defined by this epidemic, our city has defined the problem and now has a strategic means to attempt to conquer this enemy."

In 2017, "Our city has experienced challenges before. The addiction epidemic has challenged our resources and challenged our sensibilities. Nothing has ever hit our city where young and old, affluent and poor of all races and nationalities felt there was no escape."

He brought this to this community with transparency and candor. Being transparent and candor also calls attention. The national/international leaders came to Huntington to understand not only how the community was devastated by the epidemic, but how the epidemic was being dealt with, how the community was coming together to see if there were solutions; the Surgeon General, the Director for the CDC, the British Ambassador to the United States, public health officials from around the world, and most recently Melania Trump.

Former First Lady Melania Trump came to Lily's Place. And you're going to hear a lot about Lily's Place in Huntington, West Virginia. Lily's Place is one of the first places where they actually brought together mothers and

children, children who were exposed to opioids in the womb, and to work together to heal and to have treatment.

Melania Trump attended the ceremony for foster children. During Melania Trump's visit to Huntington, she viewed 453 flags that were placed in Ritter Park. Each represents a child in foster care in Cabell County. All came to Huntington to bear witness to the community's struggles.

This community has been subject to medical science and technical literature. They've been the subject of these studies of what has happened in the community and how it happened.

Members of the community have testified before Congress. Dr. Kilkenny, the Medical Director for Cabell-Huntington and West Virginia Health Department, the Physician Director told the country, as he represented cities and counties throughout the country, what was happening in Cabell County, the number of overdoses they were witnessing in Cabell County, and shared this with the world.

Books have been written to describe Huntington and Cabell County's struggles with opioid addiction. And they have been the subject of documentaries and national news coverage.

But they've also been subject, as they sit in their

living rooms or at their kitchen tables or elsewhere in the world, to headline, headline the talk about mass casualties, 26 people overdosing on heroin in four hours in a small West Virginia town, Cabell County.

It's like Dr. Kilkenny -- you'll hear a lot about naloxone saving lives, about the struggles and continued bombarding of headlines and headlines into this community.

This epidemic was undoubtedly impacted and has impacted the public health and safety of this community and throughout this country. The pain, death, and destruction to a community cannot be overstated.

With the systemic failures that Mr. Farrell talked about come national problems as well. Between 1999 and 2016, over 35,000 (verbatim) American lives were lost to opioid drug abuse.

This country had declared a public health emergency in 2017, and as recently as April 7th of 2001 [sic] renewed this declaration, again emphasizing the fact that this public health emergency is still on-going.

There is widespread consensus on the opioid crisis amongst Government and public health agencies that opioid addiction in the U.S. is an epidemic.

Your Honor, I have a number of the agencies there who all declared in one way or the other that there is a crisis that needs to be dealt with.

AmerisourceBergen, Cardinal Health, and McKesson and internal documents also show that there's a consensus of the crisis.

Mr. Farrell told you a little bit about the location of where we are in Huntington and Cabell County. West Virginia is -- and the surrounding communities are located in the heart of Appalachia, the region of the United States stretching from southern Alabama, Georgia, up to New York State. West Virginia is the only state fully encased and situated in this region.

This region is special for a lot of reasons. It has deep cultural identity and rich history. More importantly, it's known for its independent nature, its hard-working people, and its resiliency.

Cabell County, the Appalachia region is considered the epicenter of prescription drug overdose and abuse and you'll hear that throughout the trial, Your Honor, through our experts looking at the data, looking at the consequences. Cabell County is the heart of this region.

In 2008 West Virginia had the highest rate of prescription overdose deaths in the United States surpassing even motor vehicle deaths and crashes as the leading cause of accidental death.

Governor Jim Johnson -- Justice made a declaration stating, "We have a national public health emergency when it

comes to opioid use. I have been saying all along that we have an emergency in West Virginia with opioid and drug addiction. This devastating scourge is taking the lives of hundreds of thousands of our citizens every year."

In congressional hearings again specific to West Virginia, specific to the opioid distribution, the sudden influx of prescription opioids leading to the resulting increases in abuse and addiction has had a profound effect on West Virginia. Between 1990 and 2004 the number of lives lost to accidental drug overdoses in West Virginia increased 550 percent giving West Virginia the highest death rate in the United States at that time.

And we can see the comparison in the national numbers with 369 increase to the rate of drug overdose deaths in West Virginia as compared to 149 percent in the U.S.

Unfortunately, West Virginia has also seen the top rates of NAS babies, babies born exposed to opioids. West Virginia has quintupled from 2008 to 2017. In 2016 the CDC ranked West Virginia as number one in the country for babies born with NAS, exposure to opioids in the womb.

Cabell County, as Mr. Farrell talked about this morning, more than 81 million pills of hydrocodone and oxycodone were shipped into Cabell County, West Virginia, by these three defendants.

Cabell County has had the highest opioid overdose rate

in any country in the nation. With a community of less than 1,000 people, Cabell County had over 1,000 deaths, has had over 7,000 overdoses, and has over 8,000 people living today within the community who are addicted to opioids, 8,000 people today.

And, Your Honor, as we talk and have the experts in the case, the living and the dead we need to deal with. But the 8,000 people who are living with an addiction is something that is complicated and something that we need to fix.

How did this happen? How did we get here? How do we have 8,000 people today in Cabell County, less than 100,000 people? We have to go back in time. Mr. Farrell talked a little bit about the systemic failures of the defendants and what they've done.

We also have to go back in history to see what, what wasn't there. In the late 1980s and early 1990s West Virginia did not have a problem with prescription opioid drugs. West Virginia did not have a problem of addiction to opioid prescription drugs. Cabell County did not have a problem with rising overdoses to prescription opioids.

Notably, in the 1980s and early 1990s the sale and supply of prescription opioids was also very low.

This is a heat map I'm going to show you, Your Honor, from the CDC. And as you can see, in 1999 West Virginia was hardly on the map with opioid related prescription deaths.

They were almost nonexistent. Then something happened.

You'll hear from our experts that will testify about how the oxycodone sales increased. This chart, Your Honor, represents in the United States and then West Virginia the stark difference between the sales of oxycodone from 1999 to 2019, and then hydrocodone sales, opioid pills that came into West Virginia at a much higher rate into, into West Virginia from the United States.

In Cabell County you'll hear from the experts between the national sales and the West Virginia sales is off the charts when you see the amount of pills that were brought into Cabell County between 1996, that sticker Mr. Farrell put on there, the rocket that took off with the oxy beginning to come into this community.

You'll see from the experts and also from internal documents that as sales increased, opioid deaths increased and opioid treatment increased as well. From 1999 to 2010 sales, deaths, and treatment all rose.

In 2002, 2001, 2002, '3, '4, '5, '6, 2007, as sales increased and the supplies increased, so did the map of overdoses and deaths.

And, Your Honor, I'm showing you a series of CDC heat maps that have gone every year and followed the overdose rates. And in 2016, West Virginia was on the map. West Virginia and the surrounding regions were on the map for

overdose rates due to prescription opioids.

I'm going to talk about volume. As the sales went up, it created more volume. More volume created more diversion. You'll hear from both the experts about volume and diversion. And you'll hear from internal documents, internal testimony that when you have more volume, you have more diversion.

We're also going to hear, more importantly, from the law enforcement officers. Mr. Farrell told you about the 2001 oxycodone/Oxycontin hearings. Well, we had people with boots on the ground that actually were seeing what was happening both in Cabell County and Huntington.

In 2002 the Appalachia high intensity trafficking area, drug trafficking area issued reports. And you'll see these through the years. And they issue reports about various other drugs, so this is not the only one in there, but this is the one that they're really calling attention to.

Oxycontin has emerged as the most serious pharmaceutical drug threat in eastern Kentucky and southwestern West Virginia. Oxycontin addiction is the root cause of a range of criminal activity in Appalachia, HIDTA, such as robbery, theft, various types of prescription fraud.

In 2008 the Journal of American Medical Association also was looking at West Virginia. And specifically, to put this in context, they were looking at the use and abuse of

prescription narcotics and analgesics that have increased dramatically in the United States since 1990, those sales that we talked about.

The effect of this pharmacoepidemic has been most pronounced in rural states, including West Virginia, which experienced the nation's largest increase in drug overdose mortality in 1999 to 2004. The study population was all state residents who died of unintentional pharmaceutical overdoses in West Virginia in 2006.

And what they found, Your Honor, is that opioid analgesics were taken by 93.2 percent of the decedents of whom only 44 percent had ever been prescribed these drugs. The pharmaceutical diversion was associated with 63.1 percent of these deaths.

They concluded the majority of overdose deaths in West Virginia in 2006 were associated with nonmedical use and diversion of pharmaceuticals, primarily opioid analgesics.

Our Huntington Police Department also was issuing annual reports of what they were finding. In 2011 the annual report for the Huntington Police Department, "Currently, the most prevalent emerging threat to our community is the illegal diversion of powerful pain medications such as oxycodone and oxymorphone."

In 2012 the Huntington Police Department put out their health assessment. Oxycodone seizures increased

1,773 percent from 2010 totals signaling an alarming trend.

In 2012 they noted the diversion and abuse of prescription drugs in our region is an epidemic and exacts tragic costs from our communities, overburdening law enforcement, adding to prison population, overwhelming treatment facilities, undermining the employability of the workforce and, most important, devastating families, a violation of our public health, our public safety, and our public peace, Your Honor.

In 2012 you'll hear from Skip Holbrook who will be here. He wrote a letter to the Mayor, Mayor Williams. "This report is the most important document I have ever prepared for your review. The report outlines in detail the greatest threat to ever face our community, a pervasive drug culture and its associated crime."

Mr. Holbrook reported that although there has been an emergence of cheaper alternatives such as heroin, diversion and abuse of prescription drugs continues to pose a threat to our city. The most commonly diverted pharmaceuticals in our area continues to be narcotic analgesics such as oxycodone, hydrocodone, and methadone.

The diversion and abuse of controlled pharmaceutical drugs, particularly opioid-based pain relievers, will continue to be one of the most serious threats to Huntington, 2014.

And they continue, Your Honor, of just noting the fact that the diversion and abuse of prescription drugs has arguably been the largest threat to the city and starting to discuss the emergence of heroin, and the lower cost of heroin compared to the price of pharmaceutical drugs is creating significant problems for drug enforcement.

So we're seeing the boots on the ground. We're seeing the reporting of diversion. And at some point, we'll get criticized for that; we didn't do enough. We saw it coming. We involved people to help us. And we couldn't stop the deluge.

Mayor Williams in 2014, after visiting with one of the drug czars in D.C., decided that they needed to do something in a town of less than 50,000 people and a community less than 100,000 people. They took the initiative and started an Office of Drug Control Policy.

As the community in 2014 was facing more overdoses, more deaths, and rising crime, the crisis has become overwhelming.

With drugs and crime, they realized something was different. They had spent years as a community. They deal with crime. They deal with drugs. They deal with working to have peace, public safety, and public health in their community, but something was different.

They realized they could not arrest their way out of

what they were dealing with. They soon began to see that they were compelled to change their approach. They began focusing on the disease of addiction.

You'll hear from Mr. Hank Dial too, former Chief of Police and now the City Manager. And you watch the deluge of pills coming into the community and as he works day in and day out in law enforcement, it used to be us against them, us against them. We're the police. We're arresting people who are using drugs.

He came to realize this was a community struggling with opioid addiction. It was no longer us against them. It was all about us. We had to look at it differently.

This Task Force, the MODCP, established a drug addiction comprehensive approach involving prevention, treatment, and law enforcement. They worked on a strategic plan in 2015 and 2017. And we'll go over some of those and you'll hear they're working throughout the community with Cabell-Huntington, with the county, with the Health Departments, with EMS and throughout there. We'll hear about how they collected data to see what was happening.

Importantly, the strategic plan encompassed hundreds of meetings over thousands of hours of interaction of law enforcement officers, healthcare professionals, social service administrators, educators, elected officials, clergy and community activists, recovering addicts and neighborhood

groups. They went out to the community to see what's going on.

Scott Lemley will be here and he's going to -- he calls it the Listening Tour. They spent hours and hours and hours of interaction to understand what was going on, what was happening when all of a sudden they were getting 26 overdoses in four hours. They were overwhelmed.

But they took it upon themselves to do some investigation and some work. And what they found, as Mr. Lemley, the crime analyst, gathered his data and working through the community that overdose calls were going up. 911 burdened them with overdose calls.

They looked at the overdose deaths and they compared the City of Huntington and Cabell County to the State of West Virginia. And the rates were alarming of the overdose deaths compared to not only West Virginia throughout the state, but looking at national averages in other states, alarming rates.

They put together overdose maps. They needed to see where is this happening. Is it one part of the community or pervasive? The overdoses were pervasive throughout the community.

And these were things they put out for the public for us to learn to see what was going on. They started looking at the drug offenses. They went back in time. 2004, not so

bad, something they could handle. As we moved to 2014 and 2016, they found at alarming rates that drug offenses and drug crimes had greatly risen.

As part of their investigations also, they found that opioid drugs was a huge part of this. They also found in their own investigation, their self-investigation, that the Neonatal Abstinence Syndrome, babies born to mothers who were addicted to opioids, was also rising. And they found the other harms that are a result of opioid addiction throughout this community, the safety concerns of public places, some homelessness, neighborhood blight, and other things that have dealt with the opioid crisis in their community.

The data showed this from their self-investigation, and they went out to try and do what they could do with their departments with their limited resources to find some solutions.

You're going to hear from the first responders. You're going to hear from Jan Rader, Gordon Merry, and Connie Priddy, first responders who witnessed every day what was happening to this community, first responders who are there to save lives.

You'll hear from Gordon Merry, the Director of the EMS, who tracked the calls on activity. They were being overwhelmed. He will testify one overdose is too much, too

many, but that thousands of overdose calls were overwhelming.

You'll hear from Jan Rader and all of the first responders who they are the witnesses of what is happening in the community. They are the first people to see a victim of an overdose. They are the people that bring the breath back into those people with overdoses if they can save them.

Many times they're not there in time. But many times the naloxone that Your Honor will hear about is a drug administered that brings breath back into lives of a person who has overdosed, of someone who is addicted to opioids and who has overdosed.

But they also bear witness not only to the person that they're helping, but to the people surrounding them; overdoses that have a mother and a child, overdoses that have three or four people there, overdoses that may have been there yesterday and were the same person and had to treat them again with naloxone.

And you'll hear, Your Honor, some people have said, "Let them die. Why keep reviving someone who is taking and abusing opioids and overdosing?"

But these first responders will also tell you that every time they're there, every time they revive someone from opioid use, they're one step closer to recovery. And this is a huge part of our case, Your Honor, how we get to

the throws of addiction that has created such carnage in our community to get them treatment to be in our community to make it better.

So what Gordon Merry will testify about is QRT. QRT is one of the programs that they put together, Quick Response Teams, to say after an overdose, if you can get there in 72 hours -- it's better to get there as soon as you can -- but 72 hours after every overdose, they went out and visited the community. They go to that person who overdosed. They see their families.

There's a small window of time when people are ready for recovery. And if you're there, they grab ahold of it. If it's not there, they stay with their addiction. And that's a battle that we face and a battle that we've learned. The sooner you can get to people to get them into recovery, the sooner there is hope in the community.

You'll also hear from Jan Rader and Gordon Merry, Connie Priddy, and other first responders. That is part of a scene that's reviving people. It's taken a toll. They've been on thousands of calls. They have been interviewed by people from all over the world on what they've been seeing. They have witnessed how naloxone is a necessary part of this community now to revive overdoses. And they are day in and day out with EMS, and not only EMS going to get to that individual, but for the community and the sirens and every

day hearing that more overdoses are there.

The Quick Response Team goes out and quickly tries to bring hope, often recovery, and get people to be somewhere they need to be. But the toll it's taken on the first responders has also been a significant issue for this community and something as we move forward in our remedies on how we ensure that the people that are working to save the lives are taken care of as well, the people who witness overdoses and the community around them of how it's impacted death and destruction, reversing people from death and trying to bring them hope for recovery.

As Mayor Williams said in one of his state of the states, "We came to understand that we had to help the helpers. As much concern as we have for those fighting the disease of Substance Use Disorder, we had to make sure that we are directing our resources to help our own. After all, first responders need to be cared for in order for them to care for the community."

Again, Your Honor, we talk about public health, public safety, and public peace is at the heart of it.

You're going to hear, in addition to our state investigation, from Dr. Gupta. The City of Huntington-Cabell County did their own investigation. They went to see what was happening. And at the same time, the state is also looking into many of these issues. And you'll

hear about the reports and the investigations that the state did.

Dr. Gupta will testify when he first came to West Virginia, he was with the Kanawha and Charleston Health Department. He then went to serve as our Health Commissioner, the person in charge of overseeing the public, head of this community.

And the first thing that he did was say, "We need to see what is going on. You cannot fix a problem until you know what was happening."

Huntington and Cabell County could not fix their problem until they reached out to the community and what was happening.

And you'll see these reports, Your Honor, that the first thing they did, they went through all the death certificates and reviewed from 2001 to 2015.

They did a social autopsy in 2016 where they looked at all the death certificates for overdoses in West Virginia. And similar to the 2008 article that I showed in JAMA, another social autopsy, they found diversion in our community.

They also looked at the outbreak of the 26 people who overdosed in four hours in Huntington. And you'll hear testimony about these and their findings.

You'll hear, especially in the 2016 report, three out

of four people who died of a drug overdose with opioids had sought treatment weeks before and it was not available, three out of four people.

These are important investigations where they got teams together to pull the data, to review the data, and make a public record of what has happened in West Virginia.

The overdose death rates for the historical review found that Cabell County had the highest death rates of heroin at that time. The prescription opioid misuse and use of heroin and illicitly manufactured fentanyl were intertwined and deeply troubling. The epidemic of deaths involving opioids continues to worsen.

And, as I mentioned, in 2016, and we'll go over those with Dr. Gupta, tragically the three out of four people who died tried to seek help before their time of death within the last year; also the indication of diversion and the significant amount of people who had prescriptions filled 30 days before their death.

The city and county have worked hard to not only realize what they have, what they have lost, but what is it that they can do to make things better to the extent they can.

And you'll hear the testimony that with all the negativity and the destruction and what they are still witnessing, they've looked for solutions. They've always

been transparent. They've never stepped back. They're resilient. And they're doing what they can with the limited resources that they have.

You'll hear the partnerships that have been brought into this community to deal with these problems. Marshall University, Cabell-Huntington Health Department, other places have all been willingly looking to see what we can do and trying to work on programs.

Every year is different. Funding is different. Can we work through this and can we work through this problem? And you're going to hear from all of these, Your Honor, on different programs that are going to be also included when we talk about our remedies.

We have infrastructure that has started. We have a community that is energized, but a community that needs help if they're ever going to get out of this epidemic.

In addition to the City of Huntington investigation and our state investigations, when we brought this lawsuit we also brought in additional experts.

You'll hear from a number of different experts, and I'll highlight only a few on here. But you'll hear from Dr. Waller, and Mr. Farrell mentioned Dr. Waller. He's actually going to talk about addiction when he talks about the molecule.

And we have to understand if we're ever going to abate

this crisis, we have to understand not only how we got here, but what does opioids do to the brain, why is it a community problem when you have people addicted, and how that impacts a community as a whole. Dr. Waller will be, as Mr. Farrell said, he'll be the first witness to testify and tell us about how that works on that. He'll also talk about the dramatic exposures to the opioid-created public health matter.

Dr. Cicarrone will be here who also is a public health expert and he'll provide a community health perspective. The increased prescription drugs and pills led to heroin use on that. He's been on the ground. He's studied it from the ground of dealing with heroin users and understanding how they got there. And he'll testify that prescription pills were the root cause of their addiction.

You'll hear from Dr. Loudin who is formerly with the neonatal pediatrics near Marshall University. He's now moved to Charleston, South Carolina. So he's in the other Charleston. But he's witnessed for years -- he grew up in the Huntington community.

And Dr. Loudin will tell you about the number of babies and the increasing number of babies that have been born exposed to opioids. He'll tell you about how proud he is of starting the first neonatal unit that dealt specifically with babies exposed to opioids, first in the country, first

in the country to have a place where people could go and not feel ashamed and not feel judged, a mother who is addicted to opioids.

And he tells you a little bit about how that, just the fact that you could be pregnant and still be using opioids, the addiction that occurs with that, and to have a mother and child still be able to be together to the extent they can and work with them.

And you'll hear Dr. Loudin tell you how babies are treated and how they go through withdrawal with that.

And you'll hear from Dr. Nancy Young who's an expert in child welfare and children and families. And she'll tell you and testify about after they're born about the things that they have to deal with.

She'll talk to you about what I mentioned, the EMS, when they have the mothers and the children when they see them. She will testify about the foster care when said child is taken away from an addicted parent or a child witnesses the overdosing of a parent.

She'll testify about the impact the opioid crisis has had. And she'll talk about the multi-generational nature of this opioid epidemic.

You'll hear from Dr. Keyes. Dr. Keyes actually has published. Dr. Keyes is an epidemiologist and I'm not going to go extensively into all of her qualifications because

we'll have, I think, a lot of time in court, Your Honor, to talk about them in more detail.

But we have experts from, from public health, from epidemiology, from various arenas there who will testify about their area, their specific area.

Dr. Keyes is an epidemiologist. She looks at the root problem of various types of population issues. But she has a specialty in Substance Use Disorder and she spent a great amount of time in researching and publishing. And she's studied the actual rural areas and the differences of prescription opioid use and abuse in the United States.

And she'll be here to testify, after putting the City of Huntington and Cabell County under the microscope, as all these experts did, the driving force in increasing opioid related morbidity and mortality was, and continues to be, access to and widespread availability of opioids, access and availability.

You'll hear from Dr. McGuire. Dr. McGuire did something a little different. He quantifies the economic cost related to the deaths, morbidity, the neonatal abstinence syndrome, crimes and property damage and loss, and children maltreatment in the community from 2006 to 2018.

He quantifies the harms done to this community. He's looking back at what was done. And, as I've mentioned,

you've got to look backwards to move forwards.

He looks back and estimates the cost to this community from the deaths and the morbidity or mortality is in the billions of dollars. While he's looking backwards, we look forward to remediate this problem.

Your Honor, we're going to prove that these companies contributed to the epidemic and were a substantial factor in bringing this about. Mr. Farrell touched on a lot of this this morning.

I'm not going to go into detail with this, but I expect to hear the rest of the afternoon about the intervening causes or other bad actors who should take the blame for this epidemic; that other actors will tell you that they should be the responsibility and they are not responsible.

The companies are an indispensable link to this epidemic, Your Honor. There has not been any activity that was not either foreseeable under these laws and under what they knew in their own files that would have prevented them from taking responsibility. There is no break in the causal link.

And with the legal causation, we come to the remedy and recovery. And I'd like to spend some time, Your Honor, on that.

We will prove and we'll work for the next several weeks to present it to Your Honor. The companies contributed to

this epidemic. And under the law of public nuisance, we're going to describe to you our plans for recovery, our plans to heal and protect and restore this community.

I started my opening with the case that it's about public health and public safety and public peace. It's also about the healing and protecting and restoring.

We're going to present to Your Honor a plan about treatment, recovery, and prevention. We call it the abatement plan. And it's a remedial plan to work with what we've had within this community.

The volume of pills that entered this community and resulting harms can't be fixed overnight. And it is certainly something that will take a good while to fix. The remedy to restore the community is the right to public health and public safety and public peace. It will take time. It will take money. But it can be done.

We plan to present to Your Honor a detailed plan backed with evidence, backed with time and money based on formulations by experts informed by experience who studied this community and understand the needs.

The plan will deal with the four horsemen Mr. Farrell mentioned. It will deal with the community of addiction, abuse, morbidity, and mortality.

It will deal with the fact that addiction has greatly impacted our public safety and public peace and public

health and how we move forward in remedying that.

It will be a plan that also will look at the impact that it's had on police, the healthcare, first responders, employment, and families.

And it's a plan that's going to take into account the multiplying impact of addiction it's had on the community. And it's important we know of the impact because that's going to take some time to work throughout the community with this plan.

Dr. Caleb Alexander and George Barrett will be the primary witnesses and experts to testify about the plans and their experiences and how they've learned to work with communities and best practices for dealing with the opioid epidemic and making them and restoring their communities.

It may look complicated, but as Your Honor will hear throughout the trial, you'll hear through the discussions of the consequences, for every consequence there's actually something that can be done forward looking to remediate this problem.

We're going to look at treatment. We're going to look at recovery. We're going to look at special populations that prevent the opioid misuse. We're going to look at lifelines to recovery, a plan that is specific, detailed, and evidence-based.

We're going to have a plan that is consensus support on

every part of the plan that we present to Your Honor, a plan that deals with prevention, a plan that deals with treatment, a plan that deals with recovery, and a plan that deals with special populations.

And we're going to make sure, Your Honor, that with all the work that we've done to date in order to remediate this problem, we've provided a plan, a 15-year plan. That won't get us to zero, but it certainly makes a significant impact on the community.

An abatement award, Your Honor, is not a check to the plaintiffs. It's funding a program and initiatives that will be administered by the plaintiffs and their infrastructure that will be in place; the hospitals, the state, the Cabell-Huntington community that has worked so hard to date on trying to work with this problem, but there's a lot of work to do; a plan that will take into account what has been done to date, but a plan working with the experts that works with the 8,000 people who are today addicted to opioids; a plan that will prevent someone from getting addicted tomorrow; a plan that will look to ensure that our community as a whole is restored by treating opioid addiction.

The Mayor always has some good quotes. I like to put them out there, Your Honor.

"The epidemic of addiction is now so pervasive that our

standard of living and our way of life and our children's future is at stake."

Your Honor, throughout this trial we've presented, you will be presented and I've presented today with graphs and data and data points and statistics. We have to keep in mind when working and looking at this data, as we hear from first responders, as we see the rising number of calls that they're getting, that these are impacting the community and the community citizens.

Statistics are people with the tears wiped away. Our community has been ravaged by the opioid epidemic; the children, the mothers, the fathers, families, colleagues.

You'll hear from the first responders, Your Honor. They go out on runs to see their classmates. No one is untouched by this epidemic. No one has been untouched within this community. If they themselves aren't suffering, someone else is. And you'll see this throughout the testimony in this trial.

This is a story about a community. It's a story about a community and what these companies did to this community. It's a story that is not only about the devastation, but about how a group of members of the community, seemingly unphasingly unsurmountable harm, came together to restore hope, but come together knowing they cannot do this alone.

They have attempted to get funds where they can. They

cannot every day be spending and graveling and getting dollars for where they need to go. But they've made a difference, and they know they can make a difference in the future.

This epidemic is not going to get better. Substantial effort is still going to take place.

Your Honor, it's been our honor, my honor, and the honor of Mayor Williams who's here and Cabell-Huntington to be before this Court for the next several weeks.

The epidemic of addiction is pervasive. These communities cannot walk away with it, from it. These communities have faced it head-on. And we look forward to trying this case and find accountability with these companies to also shoulder this problem.

Thank you, Your Honor.

THE COURT: Thank you.

Ms. Kearse graciously did not use all of her time and I thank you for that although -- it's a little after 12:00. Let's come back at 1:30. Does that sound okay to everybody? And we'll press on and finish this afternoon.

And I understand there are going to be three hour-long arguments and you want to take a break between each one, is that right, so we don't have to interrupt anybody's argument?

(Counsel indicated an affirmative response.)

THE COURT: Okay. I'll see you at 1:30.

(Recess taken at 12:04 p.m.)

THE COURT: Mr. Nicholas, are you going next?

MR. NICHOLAS: Yes, I am, Your Honor.

THE COURT: Okay. You may proceed.

MR. NICHOLAS: Good afternoon, Your Honor.

THE COURT: Good afternoon.

MR. NICHOLAS: My name is Bob Nicholas. I represent AmerisourceBergen. With me throughout this entire trial will be Shannon McClure, Gretchen Callas and Joe Mahady.

As you already know, we are also joined in court today by our client. Elizabeth Campbell is AmerisourceBergen's Deputy General Counsel. And Chris Casalenuovo is its Head of Litigation.

Before I begin, I would like to say something about the opioid epidemic itself. The plaintiffs took time in their opening to describe its devastating effects. That is something that we all agree about. I don't think there's anyone in this courtroom who has not been affected by the opioid epidemic and at no point during this trial, at no point, will we seek to minimize its toll or its emotional impact.

But this is a lawsuit and the attack against AmerisourceBergen, the attack on AmerisourceBergen, and on

the other distributors is misplaced and it's contrived. There are reasons for the opioid epidemic, and they are obvious, but they have nothing to do with the distributors and the plaintiffs know this. They have pointed the blame in many different directions at different times. And the way that they have shifted blame, depending on the circumstances of the moment, is in and of itself extremely revealing.

The true roots of the opioid crisis will be brought out during the course of this trial, not just through our witnesses, but also through the plaintiffs' witnesses, and also through their experts.

Now, I would like to say something directly about my client, AmerisourceBergen. We will defend ourselves over the next 12 weeks in this courtroom before Your Honor because we are proud of the job we do and the role we play in the delivery of healthcare products and medicines throughout this country, because we take our job with the utmost seriousness, and because we do a good job, and because we did not cause the opioid crisis.

And having had the opportunity to say those things by way of introduction, I will now turn to the facts of the case, and I'd like to begin by outlining the most fundamental facts, sort of going to run through the course of the entire trial.

First fact. The reason that the opioid -- that opioid prescriptions increased in Cabell County and in the City of Huntington and across the country is that doctors prescribed more opioids. No one in Cabell County or Huntington got a prescription for an opioid pain medicine without a doctor. Medical practitioners, doctors in this country, determined that pain was being consistently undertreated. Undertreating pain has real consequences for people's lives and their health.

And this became a national phenomenon to the point where pain came to be considered the fifth vital sign right alongside heart rate, respiratory rate, blood pressure, temperature. Doctors and hospitals were told to pay more attention to the treatment of pain and it became part of their performance evaluation. Were they adequately addressing the issue of pain with their patients? And if they didn't perform well, their funding got cut.

Why were so many prescriptions of opioids written and dispensed in Huntington and Cabell County? Because it was the judgment of doctors that they should be. Regardless of whether these medical decisions were influenced by manufacturers like Purdue, or whether they were the result of individual doctors making decisions based on their experience, their training and, frankly, their interaction with patients who were describing pain, this had nothing to

do with the distributors. The distributors did not affect demand. Doctors prescribed more opioids, more pills.

The second fact is that we, as distributors, don't decide how many opioids can be manufactured and distributed in this country. The DEA decides. In other words, not only were we not or are we not affecting demand, we don't determine supply either for opioids or for any other controlled substance.

Every year, the DEA takes a fresh look at predicting and analyzing the likely legitimate medical need for the next year and decides how many opioids can be manufactured and distributed in the United States for the year. They set the limit, which is referred to as a quota, and year after year, in the heart of the -- of the opioid crisis, the DEA's number went up.

AmerisourceBergen and the other distributors here today had no involvement in those decisions. Were they right or wrong? Were the DEA's decisions right or wrong? It's not for us to say. And just so we're very clear, we never hit the limit.

The next fact is that AmerisourceBergen met its regulatory requirements. We were required to have a program that identifies and reports suspicious orders of controlled substances. We did that. We always had a program and we always reported suspicious orders, including to the few

pharmacies -- or for the few pharmacies that the plaintiffs want to focus on in this very case.

The way it works with suspicious orders is this: Our responsibility is to send the suspicious orders that we identify to the DEA and the DEA is supposed to determine whether, how, when, if to follow up on them. Under the regulations, distributors report suspicious orders to law enforcement. We are not law enforcement.

But it appears that the DEA did not, in fact, follow up on suspicious orders that were sent to it. And that is not just coming from us. The Office of Inspector General has examined the DEA's role in the opioid crisis. As it turns out, the OIG concluded that DEA mishandled or failed to handle suspicious orders here and elsewhere in the country for ten years.

Why? Why is that? Well, we don't know for sure, but maybe the DEA did not find suspicious orders useful. One DEA division program manager called their system "a joke", quote-unquote, "a joke". And, similarly, the West Virginia Board of Pharmacy did nothing with suspicious orders other than put them in a drawer. And that is not a turn of phrase. I'm not being clever about it. They literally put them in a drawer and did nothing else.

So, AmerisourceBergen did report suspicious orders as called for under the regulations. And we did something else

that is extremely important.

As we've already heard, all distributors submit standard monthly ARCOS data to the DEA, but AmerisourceBergen does even more, and this goes directly to the issue of transparency. We actually report every single order of a -- of controlled substances to the DEA every day. Only the DEA has all the data. The DEA doesn't allow the distributors to share each others' -- to know each others' data.

The plaintiffs want to talk about oversupply, as if we were releasing pills onto the market unfettered. That's not what happened at all. The DEA always knew, always knew how many pills were shipped, and exactly where they went, and exactly when they went, including the Cabell -- to Cabell County and Huntington. And it is only the DEA that has access to all of the information over all these years.

So, during this trial, the plaintiffs may quarrel with how many or how few suspicious orders we reported, but as a matter of actual cause and effect, it is not relevant. They're acting as if our reporting more suspicious orders would have stopped the crisis in its tracks, but that's simply not the case. There is no connection. There's not even a correlation with the number of suspicious orders we reported and any action taken.

No connection. No correlation. No causation. And

that is not a technicality. That goes to the heart of the case, causation.

The next important fact is this: The plaintiffs are trying to hold us responsible for other people's illegal conduct. The plaintiffs' entire case is predicated on the idea that we, as the distributor, are responsible for the downstream diversion of properly prescribed opioids, but they are not accusing AmerisourceBergen of allowing any diversion at all when the pills are on our watch, when we have possession of them at our warehouses, or on our trucks.

There's no allegation that any of AmerisourceBergen's 23,000-plus employees sold opioids illegally out of the back of the warehouse or lost them, lost them off a truck. Nothing like that. Plaintiffs instead are saying only that we are responsible for the diversion of pills after they have left our possession and control.

Now, first of all, it is a fact, and the plaintiffs' experts will agree with this, that the majority of diversion occurs because of the actions of family members or friends. A teenager stealing pills out of her mom's or dad's medicine cabinet. Someone illegally selling prescribed opioids to a friend or on the street. That is illegal conduct. And it is outside of our control.

The plaintiffs are also going to emphasize the role of bad doctors who are intentionally over-prescribing opioids.

This also is bad behavior, illegal behavior, over which we have no control.

And the other kind of illegal behavior that is particularly pertinent in this case, unfortunately, is more sinister. Gangs, drug cartels, and drug dealers preyed on Huntington and Cabell County in particular. Huntington became a hub for illegal drug distribution, heroin, cocaine, methamphetamines. And this continues to this day. And there are reasons for this and we'll hear about them at trial.

And while this, that, is a -- is clearly a bleaker aspect of criminal behavior than, for example, taking pills out of your parents' medicine cabinet, the two have this much in common in terms of this case. They both describe illegal conduct that we simply played no part in, but that the plaintiffs are now asking us to pay for.

The next fact is that there are reasons why West Virginia has been so hard hit. Opioids were, and they still are, prescribed in West Virginia at higher levels than elsewhere. Why is that?

As Your Honor knows, major industry in this state involves very hard physical labor, coal mining, lumber. Cancer rates are higher here than in other states. The state has an older population. West Virginia's population suffers from the highest arthritis rate in the entire

country. There are more pain conditions and there's more disability.

And, traditionally, there's been less of a focus on preventative care. People with -- people wait longer before they go to the doctor, so medical professionals do tend to be treating -- to be dealing with more advanced injuries and disease. The reality is that the area has a legitimate need for more prescription medicines, including more pain medicine, and other types of medication, too.

For example, blood pressure medication is prescribed at higher rates in West Virginia than elsewhere, as is -- as are many other medicines. Unfortunately, prior to the opioid epidemic, there are some -- there are -- these same factors led West Virginia to struggle with illegal drugs, as well. Sadly, the drug issues in this area did not start with opioids.

One more overriding fact. The City and County governments that have brought this lawsuit presided over the very epidemic that they are suing about. We, as a distributor, sent pharmaceutical products, including opioids, to licensed hospitals and pharmacies who ordered them. That's what we did.

But we are not a regulatory body, or a police force, or a Drug Task Force. There's the DEA. And then there are the local government entities that have responsibilities for

dealing with tough issues.

The City and the County were there. What did they do? Well, from 2002 to 2005, Huntington cut its police force, cut its police force, and got rid of its Drug Enforcement Unit. The County failed to even put together a Drug Enforcement -- a Drug Task Force. According to city officials, these decisions led to real consequences.

So, Scott Lemley of the Huntington Police Department Office of Drug Control Policy, who we will hear from in this trial, I think, said this: "The loss of police protection and elimination of the Drug Unit left the City in a vulnerable condition. This was soon discovered by drug dealers from large Midwestern cities such as Detroit and Columbus. It has been more than a decade since resources were cut and our area became an easy mark for individuals distributing drugs.

Within a few short years, Huntington was a regional distribution hub for various illegal drugs. Individuals from Michigan, Ohio, Georgia and Florida infected our area in the early and mid 2000s, selling various drugs."

And Mayor Williams said it more succinctly. "We had a reduction in law enforcement that opened the door, if you will."

Those who brought this lawsuit, the City and the County, along with the DEA, obviously, were in the best

position to address this crisis. They did not. Now, ten, twenty years later, they've hired lawyers. They've filed lawsuits.

In all fairness, this was their job to do in realtime. Why are we being sued by the people directly in charge of dealing with it? It's completely artificial. All of the things at issue in this trial are things that were known first and foremost to them.

Now, I'd like to introduce my client, AmerisourceBergen, if I may. AmerisourceBergen is an American company headquartered in Conshohocken, Pennsylvania. We employ about 23,000 people. We have 26 distribution centers around the country. AmerisourceBergen is not a manufacturer. We don't make opioids and we are not an opioid company. We do not make any medications.

We don't prescribe. Doctors do that. We don't dispense medications. Pharmacists do that.

AmerisourceBergen is a logistics company. What does that mean? It means we buy all types of healthcare products and medicines from 1,500 different manufacturers of those products. Our job is to store all of those products until one of our customers, a hospital or a pharmacy, needs them. And then, when a customer places an order, it is our job to deliver the products they've ordered safely and on time.

We distribute everything from shampoo, to chemotherapy

medication, to blood pressure medications. Because of the focus of this lawsuit, you might think that we just handle the products that are behind the pharmacy counter. Not so. We also handle many of the products that are in front of the pharmacy counter that are in the store, over-the-counter products. And opioids comprise less than two percent of our business.

Why are distributors needed? Why not just cut out the middle, the middleman, or let the pharmacies purchase their products directly from manufacturers? Because that would be impossible as a practical matter and, for small pharmacies, it would be impossible as a financial matter.

And so, imagine a small pharmacy trying to purchase products from hundreds of thousands of manufacturers. Having to negotiate the lowest price, handle billing, handle everything. Without a distributor, the job of ordering and receiving shipments by itself would overwhelm a hospital or a pharmacy. They wouldn't have time to do anything else. And without the distributor bearing the financial risk, smaller pharmacies wouldn't be able to get the products at a price they could afford.

Who are our customers? Nationwide, one of AmerisourceBergen's largest customers is the Department of Defense and has been for years. Hospitals comprise a major portion of our customer base, as do Hospice and long-term

care facilities. And, of course, pharmacies, chain pharmacies, and independent pharmacies, some of which are community pharmacies.

Every one of our customers in the United States that dispenses controlled substances is licensed by the DEA. Every customer in West Virginia is licensed both by the DEA and the West Virginia Board of Pharmacy.

And that license is not just a piece of paper. Pharmacies have to get licensed yearly. And that license says that they've been vetted, and they are legitimate, and that it's okay for us to sell to them. We don't distribute controlled substances to unlicensed pharmacies.

This case is focused on the negative side of opioids, but I think everyone does understand that they are important medications that meet a -- that meet a legitimate medical need. They're still on the market for a good reason. No one is calling for their removal. They are FDA approved and they are heavily regulated by the FDA and the DEA.

And the system that the FDA and the DEA have designed to accomplish this is called the Closed System of Distribution. And what that means is that every entity that plays a role in the supply chain for prescription opioids is separately registered with the DEA.

Here's the supply chain. Every person, every entity in this supply chain who touches controlled substances, except

the patient, has to be registered with the DEA to do business. They have to be vetted. They have to be approved, the manufacturers, the distributors, the hospitals, the pharmacies, the pharmacists, the doctors.

But given that we're the only ones here in this courtroom today, let's be clear about what we, the distributors, do not do. We don't design, or test, or make medicines. That's the manufacturers. We don't make medical decisions. That's doctors.

We don't decide what medicines are safe to use. That's the FDA. We don't license the doctors who prescribe medicines and we don't license the pharmacies that dispense them. That's the DEA and the State Board of Health, Boards of Health.

We don't decide how much of each controlled substance can be made or distributed each year. As we've said, that's the DEA in conjunction with the FDA. We don't dispense medicine. That's pharmacies. And we don't enforce the nation's drug laws. That's the DEA.

The plaintiffs would like to build their case on the idea that this is a smooth interactive system where everyone is working together and any one of these entities in the chain can raise a flag and completely stop diversion, but that is not how it works in the real world.

In the real world, distributors report suspicious

orders to the DEA and never hear anything back. As far as we can tell, as far as we know, no one ever looks at them. When something is suspicious, we report it. And then, nothing. Silence.

If the DEA suspects something is wrong at a pharmacy, we generally don't hear about it. DEA doesn't tell us to stop shipping to that customer. They don't tell us to cut off a customer. And as long as a pharmacy is registered and licensed, even if a distributor like AmerisourceBergen cuts them off, that pharmacy can go elsewhere.

Unless their registration is suspended, or their license is revoked by the DEA, or the State, the pharmacy can sign up with another distributor. Only DEA or the State can truly cut off the supply.

I mentioned earlier, I've already mentioned, that all participants -- I just mentioned that all participants in the supply chain for controlled substances have to be registered with the DEA. In addition, each participant, manufacturers, pharmacies, so forth, has its own regulatory requirements. Here are the two important ones that apply to distributors.

The first relates to physical securities, meaning -- physical security, meaning we have to keep controlled substances secure when they're in our possession and the requirements are very specific. They are too long to read.

I'm not going to read them.

But AmerisourceBergen has always complied with these regulations. We have sophisticated security systems, cages and vaults, and many other security measures. Controlled substances move through our system every day around the country and we keep them safe. And that is not easy.

Our trucks are targeted for hijacking. Our drivers are targeted for kidnappings. But we keep these products safe and you won't hear otherwise at any point during the course of this trial.

The second requirement is that -- is that distributors have to monitor orders for controlled substances placed by their customers and report suspicious orders to the DEA and here is the regulation. It is much shorter and I will read it.

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Now, I want to make a few points about this regulation. First, it has not changed since it was put on the books in

1971. Second, this is it. There's no other regulation we can look at, or look to, to determine what the phrase "unusual size" means, for example, or "normal pattern", or "unusual frequency".

I mean, look at how much detail is provided in the physical security requirements by contrast. And there is no standard in the regulation for what type of order monitoring system the registrant is supposed to design, just that it shall design one.

Third, the regulation says only that the distributor must inform the DEA when it discovers a suspicious order, but it does not require the distributor to stop shipment of the order.

You can see the regulation right here. It's not very long. It doesn't say anything about not shipping suspicious orders, which is why the entire industry used to ship suspicious orders. And the DEA always knew that.

And reporting and shipping made sense. If a distributor holds and doesn't ship an order, there are immediate real-life immutable ramifications. Namely, people don't get their medicines, and that's serious.

AmerisourceBergen has always complied with this second regulation, as well. It has always had an order monitoring program and it has always reported suspicious orders. The program has evolved over the years, as you might expect and

as you would hope, but it includes two levels of review.

First, the system identifies orders that need a deeper look for further review. We call those orders of interest. And, second, a human being reviews the orders of interest to determine if any orders are suspicious and those suspicious orders are reported to the DEA.

Your Honor will meet the people at AmerisourceBergen who have overseen this program. Chris Zimmerman and Steve Mays have been with AmerisourceBergen for decades and you will be able to evaluate the extent of their knowledge, their experience, and their education.

David May has a distinguished 30-year career -- or had a distinguished 30-year career with the DEA investigating and busting drug dealers before joining AmerisourceBergen in 2014 to be in charge of its Diversion Control Program, which he is to this day. All three will be here in this courtroom. And if Mr. Farrell hadn't called them, hadn't required them to come and to cross-examine in his case, we would have called them in our case.

In addition to our order monitoring program, AmerisourceBergen also has a customer due diligence program. We know our customers. The program is multifaceted. It includes verification of the customer's DEA registration and BOP license, site visits, audits, and analyzing in tremendous detail all of the ordering data from each

pharmacy. The information regarding ordering trends is extremely detailed and then constantly updated.

Now that we have, I think, described the rules of the road, let's talk about how this played out in real life. And this requires a discussion of history.

Mr. Zimmerman, Mr. May, Mr. Mays are not only going to talk about AmerisourceBergen. They're also going to talk about the DEA and AmerisourceBergen's interactions with the DEA over the years. This is a very important part of the story.

The plaintiffs' case is founded on the allegation that we did not comply with DEA regulations. That's their case. The DEA has regulated this industry since 1971. So, let's see what the DEA has been saying and doing from that period of time to today.

Let's start. The starting point is the 1971 regulation that requires reporting of suspicious orders. As I mentioned, the regulation does not require distributors to hold and not ship suspicious orders and history confirms this.

From 1996 to 1998, AmerisourceBergen developed a new computerized monitoring, order monitoring program. That program processed and shipped orders at night and any suspicious orders were reported electronically to the DEA the next morning. This was, at the time, a major advance in

technology.

AmerisourceBergen worked with the DEA on this program for two years, from '96 to '98. The DEA even allowed us to use some of their field offices as testing sites when developing the program. The DEA knew exactly what the program was and, importantly, importantly, the DEA knew that under this program, orders that were reported as suspicious were shipped. And the punch line, the key fact, the headline, is that in 1998, the DEA approved this AmerisourceBergen program in writing.

"This is to grant approval of your request to implement on a nationwide basis your newly developed system to identify and report suspicious orders for controlled substances and regulated chemicals, as required by federal regulation." And this was the operative program with DEA's knowledge and approval until 2007.

The plaintiffs today wish that the DEA had not approved our program because it makes it a lot harder for plaintiffs to blame us for anything that happened before 2007. But the DEA did approve our program.

And developing this program is not the only way that the relationship between AmerisourceBergen and the DEA was cooperative and collaborative. For example, over the years, AmerisourceBergen helped train DEA diversion investigators on-site at AmerisourceBergen distribution centers and

AmerisourceBergen assisted DEA with investigations in the particular pharmacies.

But in 2007, in 2007, everything changed. You have heard the name Joe Rannazzisi already and you're probably going to get to meet him. And even though he was in charge of the DEA's diversion effort during the heart of the opioid epidemic, he's going to walk in and point the finger at distributors, the very companies he regulated.

But Your Honor will also learn that Mr. Rannazzisi changed the relationship between the industry and the DEA and not for the better. Mr. Rannazzisi took over in 2006. By 2007, he had adopted an adversarial view toward the industry and toward the distributors specifically.

Under his regime, the DEA stopped working with us. They withdrew all prior approvals with no explanation. DEA's collaboration stopped on a dime. It ceased.

Here's a perfect example of the DEA's new antagonistic approach. In April of 2007, the DEA agents showed up at AmerisourceBergen's Orlando facility unannounced, Orlando, Florida. There were concerns back then related to a small number of internet pharmacies, which was a problem in the country at that time.

But instead of calling us and discussing their concerns or asking for us not to ship to those pharmacies, they just showed up, they padlocked the doors, they changed the locks,

and they imposed a partial shutdown for two months, an immediate partial shutdown. They didn't fine us. DEA has never fined us. But they shut that facility down for two months.

The way DEA chose to handle this issue was a total surprise; first, because we were operating a program that DEA had expressly approved in 1998, first and foremost; and, second, because AmerisourceBergen had always worked cooperatively with the DEA, always. In the past, they had discussed issues and they -- and changes with us amicably and changes were made.

How was the issue of this brief shutdown at the Orlando facility in 2007 resolved? AmerisourceBergen agreed to develop a new suspicious order monitoring program nationwide. The major change, the major change at that time, was that DEA instructed us to hold and no longer ship suspicious orders.

This is when DEA decided that it didn't want distributors to ship suspicious orders anymore and AmerisourceBergen complied and spent two months developing the new program with DEA's direct on-site input, both over the order monitoring program and our due diligence files. This new program held and did not ship suspicious orders and it had automatic next-day reporting and, again, AmerisourceBergen was the first distributor to do these

things.

And the DEA held out our program as a model at its conferences and seminars. In 2007, Chris Zimmerman and a DEA official jointly presented at the DEA'S Pharmaceutical Industry Conference and together they featured AmerisourceBergen's new program. This is contemporaneous evidence that the DEA thought AmerisourceBergen's program was good.

The other major event around 2007, and it was mentioned in one of the openings, is that DEA sent what are referred to as the "Dear Registrant letters". Plaintiffs act as if these letters would help the distributors how to report suspicious orders. To the contrary, they were confusing, they were strident, and they are not helpful.

First of all, they were just letters. They were not formal guidance. And when it comes to regulatory enforcement agencies, that matters. Second, the Dear Registrant letters did not provide clear guidance on how to report suspicious orders. Instead, they just asked a bunch of questions without providing any answers.

DEA said that it was the, quote, "sole responsibility", unquote, of the distributor to design the program and that not only were they withdrawing the past approvals, they also would not endorse any program going forward. They withdrew past approvals. They wouldn't endorse any looking forward

programs, which left us exactly nowhere.

Finally, the only real guidance that the Dear Registrant letters provided was that suspicious order monitoring should not be based on rigid formulas and should instead consider the, quote, "totality of the circumstances", unquote.

So, what did DEA mean? AmerisourceBergen and the industry, the industry overall, have repeatedly asked for more specific guidance on what that very -- what the answer to that very question for years.

The DEA is our regulator. We want to be in compliance. What did the DEA provide in response when we sought -- when we sought guidance?

Gray -- well, here's what the DEA said during a meeting to discuss these exact issues. "Gray is good." "Gray is good." And when we asked the DEA for guidance as to what constitutes a suspicious order, we got the same noncommittal response.

Sure, the regulation says an order is suspicious if it is of unusual size, pattern or frequency, but what does that mean in practice? The DEA wouldn't, didn't and won't tell us. The closest we've ever gotten to an answer is this, which was most recently provided in this very case by Mike Mapes, a former DEA official.

It's subjective. That is not particularly helpful.

The DEA obviously has the ability to be extremely specific and precise when they want to be. Just look at the specs for the cages and vaults in our warehouses. But they haven't done that with any -- with suspicious orders and that's the way it's been for years.

Next date, in 2015, the DEA appeared to finally acknowledge all of this and promised to clarify the regulation that defines suspicious orders. But more years passed and they didn't do anything.

In 2018, David May of AmerisourceBergen, AmerisourceBergen's Head of Diversion Control, wrote to the DEA and asked for a meeting on these issues. The DEA agreed to the meeting and then they cancelled it without explanation in, I believe, May of 2018. Three years later, we are still waiting for that meeting.

The last bit of history occurred only recently. Finally, in 2020, the DEA issued its long-awaited new proposed rule making, supposedly to clarify and add to the regulation. It's been 50 years. We've been through a total crisis and only now, a couple of months before this trial, does the DEA scramble to get something on the books.

AmerisourceBergen wants, and has always wanted, a collaborative relationship with its regulator and, in fact, we are hopeful that the situation is improving and will continue to improve, but it -- it does have to be said that

this most recent guidance still did not provide any clarification for the definition of a suspicious order and they completely ducked other open questions, too, such as whether or when a distributor should terminate a relationship with a particular customer. In other words, DEA's directive at bottom is that distributors should use their best judgment on these issues and AmerisourceBergen has always taken that seriously and done its best.

And this, this is what makes this lawsuit so frustrating. We've always wanted to be in compliance. We've consistently asked for more regulatory guidance and we've done our best to comply despite DEA's refusal to provide it. The plaintiffs have ignored all of that. They're trying now to rewrite history and they're trying to rewrite the regulations themselves.

I've talked about AmerisourceBergen and I've talked about what we do, but let's focus on AmerisourceBergen's business in West Virginia and in Cabell County and Huntington specifically.

Here is a list of our 31 customers in Cabell County during the years at issue in this lawsuit. You can see that for the period of 2004 to the present, AmerisourceBergen has served a diverse customer base in the Huntington-Cabell area. That includes regional hospitals, closed-door pharmacies, national and regional chain pharmacies, and

independent pharmacies.

Our two largest -- our two largest customers are Cabell Huntington Hospital and St. Mary's Medical Center. AmerisourceBergen began servicing both of these hospitals in 2004 and was their primary supplier of the full range of prescription medications.

Importantly, importantly, these hospitals serve a population whose geographic scope goes way beyond Cabell County. These are two of the five biggest hospitals in the State of West Virginia. They're very highly respected and people from neighboring cities, counties and states seek treatment there.

So, the number of pills distributed in Cabell County simply doesn't tell the whole story. A much, much wider population, not just county residents, have -- are filling prescriptions there.

AmerisourceBergen also services national and regional chain pharmacies, pharmacy locations in Huntington-Cabell, including Walgreen's, Fruth Pharmacy and Drug Emporium. And, last, AmerisourceBergen's service served a number of independent retail pharmacies, including McCloud, Ross Drug and Safescript.

And let's be direct. Alright? Plaintiffs are going to trash a couple of these independent pharmacies. They are. They've already started. They're going to criticize how the

pharmacies looked, where they were located, and their clientele. They will seek to push the blame for any questionable conduct by these pharmacies or, for that matter, by their customers back onto AmerisourceBergen, the distributor.

At trial, we will not run. We will not run from the fact that we service independent pharmacies. Half of the pharmacies in West Virginia are independent pharmacies. These pharmacies play an important role in their communities.

When the State of West Virginia had to roll out the COVID vaccine, it chose independent pharmacies to lead that effort. Some of the very same pharmacies that the plaintiffs are complaining about today have played a big part in that vaccination effort and the State has been widely recognized as a success story and a leader on this front.

Also, every one of these independent pharmacies had active licenses from the DEA and the West Virginia Board of Pharmacy throughout our time with them, which means that year after year, the DEA made a determination that it was okay for us to do business with them. In fact, many of them still have licenses today.

AmerisourceBergen monitored all of these customers. We did due diligence on all of these customers. We reported

suspicious orders for many of them. And the number of pills we shipped to these independent pharmacies is a small fraction of the total. Overall, most of the pills went to hospitals and to the chains.

Now, the plaintiffs mention Safescript in their opening, so I will respond to that. They've said that we fell down on our due diligence with Safescript, one of our 31 customers in Huntington Cabell -- in Cabell County and Huntington and that we should have cut off our relationship with them sooner. Perhaps we could have.

But here are a couple of facts to bear in mind. First, yes, Safescript was closed by the DEA, but let's look at the whole story, not just the last page of the story. AmerisourceBergen started servicing Safescript in 2004. Over the years, we reported suspicious orders to the DEA for Safescript.

In 2009, we received a subpoena from the DEA about Safescript. In 2010, the DEA asked for more information of us, from us, about Safescript. And then, we heard nothing else. The DEA did not tell us to stop servicing them. Quite the opposite. The DEA re-licensed them and the West Virginia Board of Pharmacy re-licensed them twice.

Look, the DEA was actively investigating this pharmacy. They knew every purchase and sale of every opioid, not just ours, but through ARCOS -- not just ours, but through ARCOS,

they knew every -- everything. They decided -- the DEA, they decided, and they were looking right at it, that the pharmacy should stay in business for three more years. Only then did Safescript get shut down.

DEA is the regulating body. They're the enforcement agency. We're not.

And, second, and this may actually be the most important point of all, but it doesn't take very long. It takes much shorter to say than almost anything else I've said so far.

AmerisourceBergen has not supplied Safescript since 2012. That's almost ten years. That is a long time. Too long from which to claim proximate ongoing harm. But that is the kind of evidence that the plaintiffs are going to present, decades old, and disjointed, and disconnected from the crisis for which they are seeking abatement today.

Of course, the plaintiffs are going to take every mistake they can find and put them -- put it under a huge, huge microscope, but each of these instances has another side of the story and, as the evidence will show, they are atypical.

Now, I want to just briefly address one other -- one or two other things that the plaintiffs have either said in their opening or that I think they're going to say during the trial that really don't have anything to do with the

facts of the case. The first is this:

The plaintiffs have already showed you an embarrassing e-mail from many years ago. They show Your Honor a parody. They're going to -- and they may show Your Honor several, a couple of parodies and characters that our people did not create, but did share with other coworkers.

Okay, do people send stupid e-mails at work once in awhile? Yes. Maybe not today as much as they did ten or twenty years ago, but even today, I think they still do once in awhile.

How many of these will the plaintiff show you from AmerisourceBergen? A handful. They were pulled from two decades worth of e-mails, hundreds and hundreds of thousands of documents that were poured over by a whole bunch of plaintiffs' attorneys from a whole bunch of law firms for years. And we -- and you will see just a few. Do these few e-mails have any bearing on how seriously these people took their jobs? No.

You will meet some of these people. You'll hear it from them. The answer will be and is no. Do these few e-mails have anything to do with creating or causing the opioid epidemic? They do not. This is a distraction.

The second may be -- the other distraction, which wasn't mentioned yet, but I think the plaintiffs may, so I'm going to just touch on it real fast, is what they call --

what they refer to as marketing. Some people, including these plaintiffs, believe that the opioid crisis was caused by misleading marketing by big pharmaceutical manufacturers, not distributors, manufacturers, manufacturing companies like Purdue. The distributors weren't involved in that marketing at all.

Here are a few things to know. First, we only communicated information to pharmacies. Never to doctors, never to patients. Second, anything we did communicate with the pharmacies came straight from the manufacturers and was from the FDA approved label. And, third, to the extent that AmerisourceBergen conveyed information to pharmacies, it did not drive demand. The information focused on which brand of a product the pharmacy should carry.

It's like you've ordered a soda and the question now is whether you want to get a Pepsi or a Coke. For AmerisourceBergen, and for these distributors, marketing is a non-issue. It is a distraction.

I'd like to shift for just a few more minutes now to plaintiffs' abatement plan because it is flawed and overreaching, to put it mildly. Plaintiffs only seek the cost of future abatement in Cabell County and Huntington. They are not asking for any past damages. And that is telling.

The reason the plaintiffs are not seeking past damages

is because that they -- is because they do not exist. That's the reason. The plaintiffs have not spent their own money to address the opioid epidemic, nor do they plan to.

As Beth Thompson, the County Administrator for the Cabell County Commission testified, Cabell County Emergency Medical Services had a $2.5 million dollar surplus from 2017 to 2018, none of which was allocated to address the opioid epidemic.

Similarly, Mayor Williams of Huntington testified that the City of Huntington projected a $6 million dollar surplus for 2021, none of which it intends to use to address the opioid epidemic. In fact, the mayor has explained that none of the money in the City's general fund was ever allocated to opioid rehabilitation.

But that has not stopped the plaintiffs from putting an absolutely absurd price tag, $2.6 billion dollars, on the cost of abating the opioid epidemic in Cabell County and Huntington. Their abatement plan is generic. It is a wish list. It totally lacks any connection or even reference to Cabell County or Huntington.

Remember what abatement means in this case. Abatement means money that Cabell County and Huntington need to fix an existing problem that was caused by defendants' alleged conduct. Plaintiffs' proposed future abatement plan runs afoul of this in every possible way.

First, plaintiffs' abatement plan improperly includes illegal drugs. What the evidence shows is that, today, the problem in Cabell County and Huntington is illegal drugs, not prescription opioids. That's a problem for plaintiffs. That's a problem for plaintiffs because abatement is focused on the future, not the past.

The prescription opioid crisis has receded. It's gotten better. The illegal drug problem has advanced. It's gotten worse. Plaintiffs understand this. They know this full well.

So, they're trying to vastly expand the harms at issue in this case and they're asking the Court to hold distributors responsible for drug dealers, gangs, cartels, illegal Fentanyl from Mexico and China, other illegal drugs like cocaine and methamphetamine, prescription opioids that were diverted and trafficked into Cabell County and Huntington by drug dealers from other cities like Detroit or from Florida. People who never touched a prescription opioid. Crime.

THE COURT: You've got about five minutes, Mr. Nicholas.

MR. NICHOLAS: I think I'm going to make it. I'm not sure though.

THE COURT: Well, do your best.

MR. NICHOLAS: But the plaintiffs -- I'll just say

this. It wouldn't even be accurate to call these things intervening causes because that understates it, because that implies a part of the same causal chain. This is an entirely different chain. They describe an entire world of harms caused by illegal conduct that has nothing whatsoever to do with the distributors.

The plaintiffs are also claiming that the epidemic is a result of people who received legitimate prescriptions, who then became addicted, and then returned to heroin and Fentanyl. But even as to this much smaller group, we know that is not true.

The plaintiffs' own expert will agree that there are no studies, none, that say that people who use opioids as prescribed go down this road. Many factors play into addiction, but it's extremely rare for a legitimate prescription used as prescribed to lead to addiction and, in fact, we know that only 3% of prescription opioid abusers, not users but abusers, move to heroin. So, the idea that a legitimate prescription opioid use leads to massive amounts of illegal drug use is just incorrect.

Responding to the illegal drug crisis in West Virginia is a -- is obviously a worthwhile and righteous effort, but it's not proper abatement in this case because AmerisourceBergen did not cause the illegal drug problem in Cabell County and in Huntington.

If you're -- now, just one more quick -- a couple more very, very quick things. The next problem with plaintiffs' plan is it does not address actual needs of Cabell County or Huntington specifically. It doesn't take into account what programs specifically are needed, what exists, what already are funded.

For example, Huntington's City of Solutions Program has been very successful by its own account. In fact, the evidence is going to show that the State of West Virginia has enough -- has enough funding. State officials have testified that it is more than they can use.

If Your Honor has any doubt that there's enough funding for these issues, consider how the State of West Virginia has spent other money obtained in opioid-related settlements. In 2016, the state settled lawsuits against these same three distributors on behalf of its citizens, including the citizens of Cabell County and the City of Huntington, for a total of $73 million dollars of which, of that amount, AmerisourceBergen paid $16 million dollars.

And how was that money spent? How was it used? Only a third of that settlement went to treatment. The rest went to public safety and to the Attorney General's Office. The money from an earlier settlement with Purdue paid for a fitness center and to remodel the West Virginia Police Academy.

And the abatement plan is wildly speculative. It goes out 15 years. It seeks treatment for people who do not currently suffer from opioid use disorder at all, but just people who might at some undetermined future time.

And abatement is the only remedy the plaintiffs seek here. They are not asking for injunctive relief. The weird thing is that even though the plaintiffs are claiming we caused the opioid epidemic, they don't ask the distributors make any changes to their programs. The plan doesn't even mention the distributors. The plaintiffs' abatement plan is a litigation plan. It is about money.

I'm going to read this section now that is headed "Conclusion". So, I'm going to make it or come very close.

The plaintiffs' opening presentation started with conduct and it ended with consequences. The evidence will show that the plaintiffs are wrong about conduct and that they have wildly expanded, or they're trying wildly to expand the consequences.

But put those two things aside for a moment. The biggest problem the plaintiffs have by far is that they have a huge, huge hole in the center of their case. And that is causation. It is a huge, un-fillable hole.

The evidence will show that AmerisourceBergen's alleged conduct did not cause the opioid epidemic. The plaintiffs want to accuse us of pointing fingers at other people, but

it's impossible to look at the epidemic without concentrating on doctors, on Purdue, on the failure of government agencies, and on a host of socioeconomic factors and criminal behavior.

Look at who they've pointed fingers at in the past. These plaintiffs and the State of West Virginia have blamed the manufacturers for the opioid crisis. In the complaint, in the complaint in this very case, plaintiffs have laid blame at Purdue's feet at hundreds of pages of detailed allegations.

These plaintiffs have sued pharmacies. They have sued pharmacy benefit managers. Huntington sued the organization that set hospital standards in an entirely separate lawsuit and in a government report and, again, these were not our words. The West Virginia Attorney General totally lambasted the DEA. They said the DEA's handling of this was, quote, "catastrophic", unquote.

We know -- we know that the opioid crisis has been devastating and has hit this community very, very hard, but this case is about more than the adverse impact on the community. It's about whether AmerisourceBergen created the crisis.

Our people take their job extremely seriously. I think you'll see that. Many have been with the company for decades. Many were personally affected by the opioid

crisis. We have always complied with the law.

We look forward to a full presentation of the evidence in this case, Your Honor, which we believe will lead to the conclusion that AmerisourceBergen is not the cause, it is not the problem, and it should not be found liable. I very much appreciate your time and attention. Thank you very much.

THE COURT: You virtually made it.

MR. NICHOLAS: Good. I'll take it.

THE COURT: Let's be in recess for about ten minutes and then we'll come back and do the next one.

(Recess taken)

(Proceedings resumed at 2:45 p.m.)

MS. MAINIGI: Your Honor, may I approach?

THE COURT: Yes, please.

MS. MAINIGI: Good afternoon, Your Honor.

As you know, my name is Enu Mainigi and I represent Cardinal Health.

Plaintiffs present this morning a very simple case. You heard Mr. Farrell say that distributors flooded Cabell and Huntington with opioid pills. And this oversupply, they say, must have been caused -- must have caused the drug abuse crisis in Cabell and Huntington. But the reality is not that simple. Drug abuse is real, but Cardinal Health didn't cause it.

Cardinal Health doesn't make opioids. It doesn't approve them. It doesn't set annual production levels. It doesn't market them to consumers. It doesn't prescribe them. And it doesn't fill the prescriptions or dispense them. So for plaintiffs to say Cardinal Health was the direct cause of the opioid problem simply does not add up.

Now, this morning Mr. Farrell told you that it starts with Purdue and the manufacturers. And we actually agree with that, Your Honor.

In fact, if you take a look at the plaintiffs' complaint, and I think we're on the third amended complaint, I'm going to take you through a few snippets from some different parts of it.

The plaintiffs here say this drug crisis started with a decision by Purdue and the Sackler defendants to promote opioids deceptively and illegally.

Purdue, joined by the other marketing defendants, began to promote opioids as safe, effective, and appropriate even for long-term use for routine pain conditions.

And, Your Honor, I'll go over this a little bit more later in my presentation. But Marketing Defendants, as you can see, is a defined term in the plaintiffs' complaint. And when you look it up, you see that it does not include Cardinal Health or the other distributors.

The plaintiffs go on and say Marketing Defendants'

deceptive marketing caused prescribing of opioids to skyrocket.

And the Marketing Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the state and in plaintiffs' community deceived the medical community, consumers, the state, and plaintiffs' community.

There, Your Honor, in four sentences is plaintiffs' explanation for the increase in volume of prescription opioids. And it wasn't caused by Cardinal Health.

Rather, plaintiffs actually note in their complaint that Purdue drove a change in the medical community's understanding of prescription opioids. This led doctors to routinely prescribe them for both chronic and acute pain completely legally and completely consistent with the changing standard of care.

And it's true that medical societies and boards, accreditation entities, and even the DEA, as we will see, came to believe that pain was under-treated in the United States and opioids could be and should be safely used to treat that pain.

Doctors were instructive that they could and should prescribe opioids more broadly and could face consequences if they didn't.

And then predictably, as plaintiffs allege,

prescriptions increased. But Cardinal Health does not drive the demand for opioids. We are a logistics company that gets hospitals and pharmacies the healthcare supplies that they need when they need them.

Now, that role that we play, Your Honor, typically occurs behind the scenes. But the public saw just how complex this process can be in the last year when Cardinal Health put masks, gowns, shields and other PPEs in the hands of healthcare workers who needed them as soon as possible.

Fundamentally, Your Honor, we are a mirror on what's happening in healthcare. We reflect it. We don't drive it. And it doesn't just happen with opioids. Let me give you a couple of examples.

First, think about antibiotics. For years, doctors liberally prescribed them. Then there was a concern about antibiotic resistance and the standard of care changed. And that resulted in our shipments of antibiotics decreasing as doctors prescribed them less and less often.

And then the same thing happened in the other direction with statins, Your Honor. In the '90s when statins became more widely used to reduce bad cholesterol, our shipment of new drugs, like Lipitor, went up as doctors began to more routinely prescribe them.

It's our job to make sure that if a doctor exercises his medical judgment to prescribe a medication for a patient

that the drug is available for the pharmacist to dispense. Otherwise, real patients with real problems do not get their medications. And that's not a decision a distributor should be making.

So when more doctors began prescribing more opioids because of the changing standard of care to encourage the use of opioids to treat pain, there was nothing inherently suspicious to Cardinal Health about that.

It wasn't a red flag or a black flag to us or anyone for that matter, as you will see, but, rather, a reflection of the evolving standard of care which I will walk through shortly.

In the next 50 or so minutes, Your Honor, I'm going to walk through the standard of care chronology because I think it's critical to this case. And then I'm going to hit a few other issues. One of them is illegal drugs in Cabell and Huntington.

I think Ms. Kearse told you that there was no problem in Cabell and Huntington with prescription opioids in the 1980s and the 1990s. But illegal drugs like heroin, meth, and crack cocaine have long been a source of problems in Huntington dating back to the 1980s and 1990s.

And heroin, fentanyl, and meth have for a while now been the cause of the vast majority of overdose deaths in Cabell and Huntington.

And while we're on illegal drugs, Your Honor, I'm going to spend a few minutes on the gateway theory which I know will be important here as the evidence unfolds. And then I will turn to what Cardinal Health did to meet its obligations to monitor and report suspicious orders.

And then, Your Honor, I will finally cover the plaintiffs' proposed abatement plan and why it can't be supported.

Throughout this trial, Your Honor, the fundamental question that's going to be put to this Court over and over, issue by issue, witness by witness is this: Have plaintiffs proven that the direct cause of the problem was the distributor that filled orders for FDA approved medications placed by licensed pharmacists to fill lawful prescriptions written by licensed physicians? We think the answer to that will be "no," Your Honor.

And I know we had some discussion this morning from the plaintiffs on causation. And I think that, obviously, is understood to be the issue that will be hotly contested and debated here, Your Honor.

Mr. Farrell talked a lot about notice and foreseeability in his opening statement. But in our view, that is not the legal standard for causation.

The legal standard on causation is proof of a direct relation between a plaintiffs' alleged injury and the

defendants' misconduct, a direct relationship.

And Ms. Kearse said we're an indispensable link in the causal chain. But there's no reason -- there is absolutely no reason why indispensable link in the causal chain is the basis for causation here. They have to show we are a direct link.

Mr. Farrell said that they were going to spend a lot of time talking about causation. And we welcome that because we do think it is critical ultimately to what happened here.

So, Your Honor, starting with the standard of care, I want to walk you through the key events in the evolving standard of care beginning in the second half of the '90s. And this will give you a sense of what Cardinal and others in the healthcare system were actually seeing at the time.

Now, Your Honor, you've heard reference to the DEA quota. And this is a graph of the DEA quota for opioids. It's based on production quota notices the DEA published in the Federal Register.

And the quota, Your Honor, represents the DEA's determination of what the legitimate medical need is for opioids during these particular years. It is the DEA that determines how much an opioid needs to be manufactured or can be manufactured for a particular year. And you will see, Your Honor, that every year virtually from 1998 to 2013 the DEA increased its opioid quota.

Now, we're going to add the standard of care timeline on top of this chart. I want to draw your attention, Your Honor, to the fact that the DEA quota chart that I've put up here has essentially the same trend line as you saw in Mr. Farrell's chart that he had up over here as part of his presentation.

And ultimately it is the DEA quota and what the DEA authorizes that ultimately determines how much gets manufactured, and then ultimately how much may get prescribed and distributed.

So I do agree with Mr. Farrell that it began with Oxycontin when Purdue in 1996, after obtaining FDA approval, launched Oxycontin, a new time-release opioid. That was the beginning of a fundamental shift in the medical standard of care.

And the plaintiffs once again say it best in their complaint. They say prior to Purdue's launch of Oxycontin, no drug company had ever promoted such a pure, high-strength, Schedule II narcotic to so wide an audience of general practitioners.

And according to the plaintiffs here, Purdue, through its marketing, promoted the concept that pain was under-treated and that opioids could not be used.

So it was no surprise, Your Honor, that by 1998 we began to see a change in prescribing guidelines from the

medical community.

In 1998 the Federation of State Medical Boards, which is essentially the parent organization for state medical boards nationwide, issued new model guidelines for the use of controlled substances for the treatment of pain.

These guidelines made clear that opioids may be essential in the treatment of acute and chronic pain, Your Honor. And they also made clear that doctors would not face discipline for prescribing opioids for legitimate purposes.

Now, where is the DEA? Soon after these guidelines came out, the DEA endorsed the medical board's 1998 model guidelines as consistent with the DEA's position on pain.

That same year, Your Honor, 1998, the West Virginia Legislature joined with many other states in passing legislation promoting the treatment of pain. And they called it the West Virginia Intractable Pain Act.

And what that act did, Your Honor, was legally protect doctors from punishment for treating intractable or chronic pain with opioids.

And among other things, the act says that a physician shall not be subject to disciplinary sanctions or criminal punishment for prescribing opioids to treat chronic pain.

Then, Your Honor, in an official statement in 2001, the DEA went even further in urging opioids for the treatment of pain.

Along with 21, 21 medical societies, the DEA noted that under-treatment of pain is a serious problem and urged doctors to treat pain emanating from chronic conditions aggressively using opioids.

And the DEA went on to say that for many patients, opioids are the most effective way to treat their pain and it is only -- and is often the only treatment option that works.

That same year, Your Honor, in 2001, the Joint Commission, also known as JCAHO, the entity responsible for accrediting hospitals nationwide, they adopted standards also that required assessing pain in all patients.

And you heard some reference to it earlier, Your Honor. The new accreditation requirements came to be known as the Fifth Vital Sign. And they put pain, as you heard earlier, on the same level as measuring your pulse and your blood pressure.

Your Honor, you've probably seen these types of pain scales when the doctor asks you to write your pain level. Doctors were now being required to ask every single person if they were in pain and, if so, to treat it.

What was the easiest way for a doctor to treat complaints of pain? By prescribing an opioid.

The plaintiffs agree in their complaint that this was another critical moment in the changing standard of care.

And, in fact, in 2017, the City of Huntington agreed and they actually sued the Joint Commission, as I think you heard Mr. Nicholas make a reference. The City of Huntington sued the Joint Commission for its alleged role in causing the opioid epidemic.

They understood that the changing standard of care had something to do with all of this. And, in fact, they hired -- I think I heard the name Rusty Webb earlier. They hired Mr. Webb to bring that lawsuit. And that lawsuit was dismissed, but they're in the process of trying to revive that lawsuit at this point.

So in their complaint, Your Honor, this is Huntington blaming the Joint Commission. They said that in 2001 the Joint Commission teamed with Purdue and other manufacturers to issue pain management standards that grossly misrepresented the addictive qualities of opioids.

And according to Huntington, the Joint Commission standards effectively forced doctors to follow the new standard of care and prescribe opioids to keep their hospitals in business.

Next in 2004, Your Honor, the Federation of State Medical Boards doubled down. They came back with an updated model policy further urging the treatment of pain. And in its updated model policy, the Federation noted that both acute and chronic pain continue to be under-treated in 2004

and even threatened investigation of the under-treatment of pain.

Now, as the plaintiffs say in their third amended complaint, these guidelines, of course, affected prescribing. The 1998 guidelines and the updated 2004 version, as they note, were posted on-line and were available to and intended to reach physicians nationwide, including in the City of Huntington.

Now, in 2005 the West Virginia Board of Medicine adopted the medical board's new model policy. And their policy, the West Virginia Medical Board's policy, also emphasized that treatment of pain is integral to the practice of medicine. And they recognized that opioids may be essential to treating all types of pain.

Now, doctors, of course, followed all of these guidelines recommended by the Board of Medicine, the Joint Commission, and the DEA.

And as plaintiffs say in their complaint, treatment guidelines are particularly important to the Marketing Defendants in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain.

Now, if that was not enough, during the same time period that we're talking about, all the way through 2016,

doctors also faced lawsuits by private plaintiffs' lawyers for the under-treatment of pain.

And this included the county police council in this case whose firm, Greene Ketchum as late as 2016, less than a year before this case got filed, that firm solicited patients to sue their doctors over not being given enough pain medication.

Now, during this entire time period, the DEA didn't think doctors were doing anything suspicious by prescribing more opioids.

In 2006, for example, the DEA, in response to questions from the medical community, issued a policy statement assuring doctors that increased prescribing of opioids was justified. So this is the same year, Your Honor, we heard -- and you will hear a lot about Mr. Rannazzisi and the Rannazzisi letter that came out in 2006 and the subsequent year. This same year the DEA is taking the position, 2006, that doctors are justified in increasing their prescribing for opioids.

Now, if we take a look at the policy statement, Your Honor, one of the headlines in the statement says, "The number of physicians who prescribe controlled substances in violation of the CSA," Controlled Substances Act, "is extremely small and there is no DEA crackdown on physicians."

And it goes on to say that the overwhelming majority of doctors prescribe for legitimate medical purposes. And, of course, Your Honor, the DEA determines if there is legitimate medical need when they set the quota.

The DEA also made clear that nearly every prescription issued by a physician in the United States is for a legitimate medical purpose.

Now, this was not just the view of the DEA, but this perspective lasted at the DEA at least until 2012 when Joe Rannazzisi, who you've already heard a lot about and you will continue to hear a lot about, Mr. Rannazzisi, who by this time in 2012 was running the DEA, parts of the DEA, and he'll be a witness you heard here for the plaintiff. Mr. Rannazzisi in 2012 told Congress that 99 percent of doctors were prescribing opioids appropriately.

Here is his congressional testimony. He testified -- he got asked, "Would you favor under the Controlled Substances Act to create a stricter requirement, legal requirement for the most problematic drugs?"

And Mr. Rannazzisi gave a long answer. But part of his answer, he testified that 99 percent of the doctors are perfect, 99 percent, and that just one percent of doctors are the ones who prescribe for illegitimate purposes or don't make a medical determination before they prescribe.

Now, Your Honor, not only did the DEA determine how

many opioids were produced each year, but it also knew exactly where those pills were going and when. And you heard a little bit about that from Mr. Farrell, but I want to clarify a few things that got discussed.

First is the ARCOS data. And I think you heard Mr. Farrell reference the fact that all DEA licensed distributors like Cardinal tell the DEA each and every pill they ship and to what pharmacy they ship it.

And this is part of what makes up the ARCOS data and it allows the DEA to determine the total volume of prescriptions distributed to every state, every county, and every pharmacy in the country.

And if there are too many prescriptions going to a particular county for opioids, or a particular pharmacy, the DEA knew about that.

But the DEA, Your Honor, -- this is important. The DEA is not the only one that has that information. Starting in 2003, the DEA posted this information on its website for all to see. It posted total distribution volume by three-digit zip code prefix.

So the plaintiffs here, and everyone else, could see quarter by quarter, year by year the total volume of opioids distributed; for example, as you'll see from this chart, Your Honor, to the 255 and 257 zip codes.

And I think that there -- it was not exactly clear to

me, Your Honor, and I assume the evidence will unfold and we'll see it. It wasn't clear to me whether there was a thought that this information was publicly available or not.

I think Mr. Farrell referred to Mr. Eyre's reporting as the first time the ARCOS data was publicly available. But the reality is that the chart that Mr. Farrell had up here for most of his opening statement, that chart could have been put together beginning in 2003 quarter by quarter.

That chart didn't need the release of ARCOS data that either Mr. Eyre received or that we provided during the course of discovery in this case. It was available to the plaintiffs and everybody else to see quarter by quarter.

But we will continue, I'm sure, during the course of the trial to hear about the sensationalized volume and for the defendants to receive blame for those volumes. But keep in mind, Your Honor, those pills shipped because doctors wrote prescriptions for them and the DEA knew about every pill to every pharmacy. And for 18 years, these volumes down to the zip code level have been known to everyone out there.

Now, despite the fact that doctors and medical boards and the DEA all agree this volume of medication was necessary and appropriate, plaintiffs are now saying the distributors were the ones that should have known better and should have said "no." And that doesn't make any sense.

Now, what happened to the DEA quotas, Your Honor? Well, it's not until 2013 that we see the DEA quotas level off. And then there's a significant downward trajectory after 2016 when the CDC passes new chronic pain opioid guidelines.

And in 2016, Your Honor, the CDC determined that there was a lack of guidance to primary care physicians about when to prescribe opioids, and they issued new guidelines meant to limit prescribing opioids by primary care physicians.

Now, Your Honor, the CDC's evaluation and re-evaluation of opioid prescribing was done against the backdrop by that point in time of everyone, the entire medical community re-evaluating the use of opioids to treat pain.

The new guidelines, though, encouraged doctors to use the lowest effective dose for chronic pain. And for acute pain the CDC guidelines in 2016 told doctors to use no greater quantity than they needed ultimately, and noted three days or less will often be sufficient.

So gone or starting to be gone by this point in time, Your Honor, were the days of receiving a month's worth of pain medication after a procedure.

Now, what was West Virginia doing in this time period? Well, they followed what the national guidelines were doing. And that same year, in 2016, they followed the CDC lead and they convened a group of experts to discuss decreasing the

use of opioids.

They published additional guidance called the Safe and Effective Management of Pain. And building on the CDC guidelines, the West Virginia guidelines gave doctors some additional details on how to treat pain in a way that limited prescribing of opioids. They included directions like screening for risk of substance misuse before prescribing opioids as, as an example.

Now, West Virginia continued to push to decrease opioid prescribing. And in 2018, West Virginia passed the Opioid Reduction Act. And it was designed to do exactly what it sounds like. The act required that before prescribing opioids, a practitioner had to inform the patient about the risks associated with opioids. And it limited, it limited a doctor from issuing an initial opioid prescription for more than a seven-day supply.

Now, looking back at the opioid prescribing trends in West Virginia over the years, the evidence at trial, Your Honor, will show that in addition to the standard of care that was occurring all over the country, these changes in the standard of care in the last two decades, there were unique additional forces that were at work in West Virginia and Cabell and Huntington that led to even greater prescribing than in the nation as a whole.

And I think you heard a little bit from Mr. Nicholas on

that. But during the trial you're going to hear from one of our experts, Dr. Tim Deer, who's been a practicing physician in West Virginia for nearly three decades.

And this is Dr. Deer. He's one of our experts and he is probably West Virginia's foremost pain expert. He was the Chairman at the West Virginia Expert Pain Management Panel which is a collection of the experts, state officials, experts from Marshall and other schools who put together the Safe and Effective Management of Pain Guidelines in 2016 that we were talking about earlier.

In addition to going through the standard of care and the evolution of the standard of care, Dr. Deer is going to come here and testify and explain why there were factors unique to West Virginia that predictably led to more increased prescribing than we saw in other parts of the country.

First, he will testify that a greater share of West Virginians across ages suffer from conditions that cause or contribute to chronic pain.

Second, compared to the nation as a whole, West Virginia's population is older.

And, third, Dr. Deer will explain that West Virginia has more workers in industry, physically demanding jobs that lead to the type of injuries for which opioids were being prescribed for a substantial period of time.

And another thing I think Mr. Nicholas alluded to, keep in behind that the pills coming into Cabell and Huntington pharmacies and hospitals and medical institutions aren't just going to Cabell County residents, Your Honor.

The evidence will show that Cabell County has long been a healthcare hub for the Huntington-Ashland Metro Area with patients traveling from other parts of West Virginia to institutions like Marshall for treatment and procedures.

So you can't just compare the number of pills coming into Cabell and Huntington to the number of people within the county limits. And I think that's an important distinction.

Now, we heard this morning that we flooded Cabell and Huntington with pills. And there were some different numbers thrown about. And I think there will be a lot of numbers thrown around during the plaintiffs' case in terms of describing in a variety of ways how many pills were actually available for the people of Huntington and Cabell.

But the evidence is going to show, Your Honor, that when you have as many legitimate acute and chronic pain patients as you do in West Virginia that the number of pills can add up quickly.

Let me give you an example. So a patient who is prescribed opioids for chronic pain often takes, Your Honor, at least three pills a day every day. And that adds up to

90 pills each month and 1,095 pills each year every year of their life. And that's on the lower end. If it's six pills a day, which might have been more the norm at various points in time, that comes out to 180 pills per month and 2,190 pills a year.

Now, at those rates, fewer than 1,000 chronic pain patients can account for one or two million doses a year, Your Honor. And if just five percent of the population in Cabell and Huntington were receiving prescription opioids for chronic pain, that alone could account for five to ten million doses in a single year, Your Honor.

And that does not even include -- that's just chronic pain, Your Honor. It doesn't include the patients who have received prescription opioids after surgery to help with cancer pain or opioids in the Hospice setting.

Now, plaintiffs' own expert, Lacey Keller, she said that there were around four to six hundred physicians in Cabell and Huntington that were prescribing opioids from 1997 to 2017.

So with more doctors prescribing significantly more opioids to treat chronic pain over the years, that obviously has a huge impact on how much medication a pharmacy needs to order from a distributor like Cardinal. You can see how the numbers can add up quickly.

And that's obviously, Your Honor, against the backdrop

of the evolving standard of care.

Your Honor, I know this is a complicated looking board, but it's a board that contains all of the players that are involved in the system of distribution.

So, Your Honor, as we look at this, and we've talked about a lot of them, it was not suspicious that Cardinal Health was getting more orders for opioids. As I said before, we, as a distributor, are a mirror on what's happening in healthcare. We reflect it. We don't drive it.

Increased prescribing of opioids by doctors to individuals in these years, the past few decades, was absolutely a predictable result of a standard of care that approved of and recommended the use of opioids for the long-term treatment of chronic pain.

And that increased prescribing, Your Honor, that was not suspicious to the medical boards. Increased prescribing was not suspicious to the Board of Pharmacy or the pharmacies that they licensed.

Increased prescribing wasn't suspicious to the Joint Commission or the hospitals they were accrediting.

Increased prescribing was not suspicious to Medicaid, Medicare, and private insurers who paid for those opioids knowing which doctors were prescribing opioids and which patients were taking them.

And increased prescribing wasn't suspicious, Your

Honor, to the FDA who approved the drugs, the manufacturers, or to the DEA which increased the annual quota nearly 40 fold over 15 years.

But why would it have been suspicious to Cardinal? If Cardinal is looking downstream, it sees what everyone else sees too, that doctors across the country are prescribing more opioids.

And if it looks upstream, it sees that the DEA is publicly saying that 99 percent of doctors are prescribing opioids appropriately. And the DEA is finding that if there is a legitimate medical need during this entire time to keep increasing the amount of opioids that are being manufactured.

So, Your Honor, in retrospect, as we think through the standard of care, was the change, the evolution in the standard of care right or wrong? Should doctors have been prescribing fewer opioids?

Those are certainly legitimate public policy and public health questions, but they're not the legal questions we're here to answer.

For the purpose of this lawsuit, two things matter.

Number one, the historical fact that the standard of care changed. Number two, distributors didn't do anything to cause the change in the standard of care.

I want to address marketing for a moment, Your Honor,

because I think that the plaintiffs well understand that the standard of care evolved and that obviously distributors cannot drive doctors to prescribe more. And that has always been -- the changed standard of care has always been a barrier to the plaintiffs' case because it stops causation.

So I think that we've already seen evidence that the plaintiffs are going to try to get around that by belatedly trying to tie distributors to the manufacturers' marketing.

Now, if we come back to the third amended complaint of the plaintiffs, I think I've told you that Marketing, Defendants, capital M capital D, was a defined term by the plaintiffs in their third amended complain. So they've had a few rounds of this complaint.

The Marketing Defendants includes only the manufacturers, Your Honor. It does not include Cardinal Health.

And, in fact, if you look at that same complaint for the hundreds of pages that it goes on, you're not going to see any specific call-out or mention of Cardinal Health and marketing.

But here's what the evidence will show if the issue of marketing becomes one that we have to focus on at trial.

The evidence will show that our primary customers, our pharmacies, and because we have pharmacies as customers, we have platforms that allow manufacturers to pass along

information about their products to pharmacies and pharmacists. This is basic stuff like what medications are available and how to order them.

And the evidence will show that this is completely different than the manufacturer marketing that plaintiffs say affected prescribing by doctors.

And as to the materials themselves, as our pharmaceutical supply chain expert, Adam Fein, will explain in court, Your Honor, the information that Cardinal Health passed along just to let pharmacies know what medications were available and for what price, that was what the purpose of that information was.

And that way, if a pharmacy could have that medication in stock, if the doctors wanted to write prescriptions for them consistent with the standard of care that we talked about.

The bottom line is, Your Honor, Cardinal Health does not seek approval of any drugs from the FDA. We don't write the labels. And we don't create the ad content. We don't create the messaging about these medications' risks and benefits. We don't send sales reps to doctors' offices. And we don't market opioid medications to consumers. And we don't convince doctors, Your Honor, to write more prescriptions.

So, Your Honor, let me turn to the second issue which

is the impact of illegal drugs.

This issue of illegal drugs is a really uncomfortable fact for the plaintiffs. They hardly talked about it this morning. The problem is for them for years now, the key drug problem in Cabell and Huntington has been illegal drugs, not prescription drugs; illegal drugs including heroin, meth, and fentanyl.

Now, the evidence is going to show at trial, Your Honor, that the illegal drug problem in Cabell County is not new. Location has always played a big role because it sits right along the interstate highway and it's an easy target for out-of-state dealers.

And as you will hear from several witnesses, including the plaintiffs, that location, combined with economic challenges, has created a severe drug problem in Cabell and Huntington long before prescription opioids were at issue.

The evidence will show that for the last several years, most overdose deaths that involved opioids involved illegal opioids. And law enforcement officers in Cabell and Huntington will confirm that illegal drug dealing and Cartel activity are, in fact, a major cause of the drug problem. And there's just a few pieces of evidence that I'll show you right now, Your Honor, that further supports that.

In 2015 the Huntington Mayor's Office of Drug Control Policy put out a report and it basically concluded that

heroin was the problem. They noted the recent deadly resurgence of heroin addiction and the public health crisis associated with it. And it was, in fact, the heroin problem, Your Honor, that led to the creation of that office in 2014.

Another example: Within the last few years, West Virginia has received federal grant money to deal with prescription opioids. But West Virginia has gone back and asked Congress if they could spend the money on meth instead which is not an opioid.

And that's what this is an example of. Commissioner Christina Mullins of the DHHR in October, 2019, was writing to Congress asking that they give them, West Virginia, the flexibility. And she notes in her letter, "Opioid overdose rates have begun to drop while overdose rates involving methamphetamine have risen sharply."

Now, Cardinal Health, of course, has nothing to do with illegal drugs and their distribution, but that is what plaintiffs are seeking money to address is really problems with illegal drugs.

Now, Your Honor, just like with the changing standard of care, the illegal drug issue creates serious causation issues for the plaintiffs. They try to get around this issue with a heavy reliance on the gateway theory. And they say legitimate prescription opioid use is a gateway to

illegal drug use. And that's an easy concept to pick up and the popular press has picked up on it, and a lot of people think that they know this is true. But the science just does not back this up.

You'll hear the plaintiffs during the course of the trial, for example, refer to an 80 percent statistic. And they want you to believe that this means 80 percent of heroin users started with prescription opioids. But that's wrong and there's no study, Your Honor, that says that.

What the number actually stands for is that 80 percent of people who used heroin had previously abused prescription opioids. So they weren't using them legally and under a doctor's care, Your Honor. So we're talking about the unsurprising fact, Your Honor, that many people who use heroin illegally also use prescription drugs.

THE COURT: You've got about 10 minutes left. I thought I'd give you a heads-up.

MS. MAINIGI: Thank you, Your Honor.

And that 80 percent statistic shows what all the other studies show. People who have the disease of addiction, people who are prone to abuse one drug, those people are also prone to abuse another drug.

And as Ms. Bierstein told Your Honor in a recent argument, correlation does not equal causation.

Now, if we really focused on the supposed gateway from

prescription drugs, Your Honor, to heroin, one of the stats that emerges from one of plaintiffs' own studies, but they don't lake to cite it because the number is so small, is that among people who misuse prescription opioids, only 3.6 percent went on to use heroin.

And when it comes to the question of what percentage of people who legally use prescription opioids as prescribed, the ones that use heroin, that is an unknown number. But it obviously has to be smaller than 3.6 percent.

Your Honor, I'm going to jump ahead to Cardinal's Suspicious Order Monitoring System.

So, Your Honor, the evidence will show that the DEA significantly changed its guidance and expectations. And we're going to review all of that, whether it's with some of our own people or some of the former DEA folks that are going to testify here over the years, and changed and evolved in their interpretation of the, of the relevant regulation.

And Cardinal Health System has evolved over the years in response to that changing guidance and we've regularly told the DEA what we were doing. And during trial you'll hear from our anti-diversion professionals. They're also being called in the plaintiffs' case. And they'll explain essentially how our Suspicious Order Monitoring System works. There's three parts to it that I'll, I'll cover

briefly, Your Honor.

One is know your customer. And as our professionals will go over, what we do when we take on a new pharmacy or a hospital is we get a lot of information from them. We look for a lot of things that the DEA has said are red flags, possible diversion, and any special characteristics about that particular customer. And not every customer passes our process. And there are a lot of customers we've chosen not to do business with because they didn't meet our standards.

The second part of the process is what we refer to as Electronic Order Monitoring. And what that is, Your Honor, as you can see, is when we set up a pharmacy as a customer, we establish a threshold that's specific to each kind of drug that the customer orders.

And when we talk about the orders that Cardinal Health reviews, keep in mind, Your Honor, we're talking about both orders from pharmacies, not individual prescriptions which, obviously, distributors can't see because of the privacy information.

So the threshold limits how much that pharmacy can order of each controlled substance. And that's based on a number of different factories and assessments that our anti-diversion team will ultimately explain.

But the bottom line is our system automatically blocks orders by customers that are over the threshold limit. And

that means the order does not ship until Cardinal Health employees take a careful look at that. And then the cancelled orders are reported to the DEA as suspicious orders.

The third part of our program is essentially the investigations or the on-going monitoring of our customers for any sign of potential diversion. And we've got a special Review Committee that reviews large volume customers.

And then for all of our customers, we have a team of folks, investigators who go out to inspect pharmacies and check signs of potential diversion. And our sales staff are also trained to look for signs of potential diversion.

We'll go over the details of this at trial, Your Honor. But one thing I will ask you to pay particular attention to is the time period so that they do not get conflated.

The reality is that with respect to Cardinal Health Systems, plaintiffs and their experts really have no complaints about them after 2012. So they're not going to talk about the post-2012 period to the present very often when it comes to our systems. And I suspect that's why we heard from Mr. Farrell post-2012 about Cardinal's membership in the had and all of the things associated with that organization.

But you are going to hear them reach back in time to

talk about what our system was in 2008, 2009, and maybe even 2003 and 2004.

And the evidence will show, Your Honor, that across all time periods, we kept the DEA updated about how our system was working. And we tried to work with the DEA to ensure that we were in compliance.

Let me give you just one example. One of the things you'll hear plaintiffs specifically criticize about Cardinal Health is its reporting of suspicious orders before 2008.

Now, you heard that -- you heard Mr. Nicholas talk about that earlier time period and the do-not-ship requirement.

This is testimony from the deposition in the MDL of Kyle Wright. Mr. Wright is now a paid expert for the plaintiffs. But at this deposition, he's being deposed as a fact witness. And he's a former DEA diversion investigator who had ownership over the receipt of reporting from distributors like Cardinal.

And what he testified to, Your Honor, was that the type of reports Cardinal was submitting to the DEA in the time period through 2005 and then subsequently were blessed and authorized by the DEA.

So is our system from today better than it was 10 years ago? Of course it is. And was our system from 10 years ago better than the one from 15 years ago? It was. And that's

how it works and that's true of most systems we have in society.

But that does not mean the systems that we had in place before were unreasonable for those time periods. And that's really the standard, Your Honor, that would have to be measured.

Mr. Farrell spent some time also talking about settlements, Your Honor. And we'll get into that perhaps at trial as well. But one critical fact related to Cardinal's DEA settlement, neither one of them had anything to do with West Virginia. And I think that's an important fact that may be a threshold issue for, for further discussion.

When it comes to West Virginia, Your Honor, I do want to also point out that within Cabell and Huntington there were distributors that provided opioids to pharmacies that are not here as part of this litigation, so not part of the Big Three, the so-called Big Three.

And according to plaintiffs' own expert, Dr. McCann, Cardinal Health distributed only about 17 percent of the dosage units of oxy and hydro in Cabell-Huntington from 2006 to 2014.

Your Honor, I'll just touch on a few brief points on --

THE COURT: You've got about two minutes. Can you do it in two minutes?

MS. MAINIGI: I'm going to try, Your Honor.

THE COURT: Okay.

MS. MAINIGI: Your Honor, --

THE COURT: I hate to cut you off, but I've got to be an umpire and enforce the rules.

MS. MAINIGI: I understand, Your Honor.

I think just a couple of points on abatement that I want to make.

I think you'll hear evidence about Cabell County never really trying to address the opioid problem because it didn't think it had the ability to do so. And I think that there will be evidence that comes in, Your Honor, also about the state having excess funds, essentially, to treat the opioid problem, excess funds and facilities that could be used by Cabell County and Huntington residents.

And then an additional point I want to show Your Honor is -- let me jump ahead here. These folks are local experts that came up, came up with a resiliency plan at Mr. Farrell's direction.

Their resiliency plan, which was a blank check, they were told that they had a blank check, when they thought about their pie-in-the-sky ideas for abatement and treatment, the number they came up with, Your Honor, was 50 million, $50 million over 40 years.

Then what happened is plaintiffs brought in a different expert. And that different expert has now come up with an

abatement plan that is 1.68 billion simply for treatment alone over 15 years. And, so, I think you will hear some testimony about that, Your Honor.

And, basically, Your Honor, we look forward to hearing the evidence here at trial. So that is why we, Cardinal Health, do welcome trial.

Plaintiffs' case is very long on rhetoric but very short on causation and I do think that's where the battle ground is going to be, Your Honor. It's their burden to prove it and this trial will show that they will not be able to prove causation.

Thank you, Your Honor.

THE COURT: Thank you.

Let's come back right at 4:00 and we'll finish up.

(Recess taken from 3:48 p.m. until 4:02 p.m.)

MR. SCHMIDT: Thank you, Your Honor. If I may start off with a mea culpa, we did not sit down and go through our slides together, so there will be a few that Your Honor's already heard of. I'll try to be efficient, but I think Your Honor will see we approached the issues from different angles and sometimes a little differently.

Your Honor, the central issue in this case, the central dispute is easily and simply stated: Causation. They allege conduct. They allege consequences. They never link those two.

The conduct they allege -- the misconduct they allege we will dispute and the facts will not support their claims of misconduct. The consequences they cite, if by consequences they mean harm, there is no dispute about the harm from the opioid crisis.

The dispute lies in the link between those two things, their allegations that specific misconduct of ours caused the entire opioid crisis. The facts will not support that.

Every McKesson distribution into Huntington and Cabell County was because of a doctor, so that when a doctor wrote a prescription and a patient took it to a pharmacy to fill it, it would be available.

Every one of those prescriptions dispensed was supposed to be dispensed because of a doctor sitting across from a patient acting as only doctors do, only authorized prescribers do, and making a judgment about that patient as to whether the medication was appropriate for them.

Those facts alone prevent them from showing causation. And in many ways, their lawsuit depends on disregarding those facts.

But they go further. The face of the opioid crisis today in 2021 is heroin and illicit fentanyl, products McKesson has never touched, that are marketed, made, trafficked by criminal organizations that McKesson has nothing to do with.

No set of facts will be able to link that affliction to McKesson's conduct. And there's no stretching of public nuisance law that can allow for a finding of causation in those circumstances.

Those are the facts, that's the evidence, and that's the proof I'll focus on today and that we'll focus on throughout our case.

In terms of my client, my client is McKesson. McKesson is a distribution company. That means it delivers medications from the manufacturers that make them to the pharmacies and hospitals that dispense them. It does that for all types of medications; inhalers, insulin, vaccines, cancer medications.

A company like Purdue Pharma primarily makes opioids. It's an opioid company. A company like McKesson covers all medications. It's a medication company. And because it's a medication company, that includes prescription opioids even if they're a small part of the total prescription medications that McKesson distributes.

Why is McKesson in this case? It's in this case because of that role of delivering medicines from manufacturers to pharmacies and hospitals licensed by the State of West Virginia, registered by the DEA.

It's not in this case because it prescribes opioids. It doesn't. It's not in this case because it's a named

marketing defendant in the complaint governing this case. It's not.

It's not in this case because it approves or sets quotas for opioids. That's the DEA and the FDA.

It doesn't dispense opioids. That's pharmacies. And it doesn't approve the doctors and the pharmacists who handle opioids. That's regulators.

This is the distribution chain. I'm a little hesitant to put this up, Your Honor. You've already seen four different versions of this. This will be yet another version of this. I'll keep it short. It starts with doctors.

THE COURT: I have a lot bigger problems than trying to figure that one out.

MR. SCHMIDT: Yes, that's right.

It starts with doctors. They give a prescription to a patient. The patient goes to the pharmacy. They get the medication. The way the pharmacy gets the medication is the manufacturer makes it. The distributor ships it to the pharmacy.

Here's why I wanted to show this yet again and I'm sorry for showing it yet again. Their lawsuit depends on ignoring almost every part of this chain. The doctor is the central initiating force in every prescription medication. They want the Court to look beyond that.

Patients, manufacturers that market and make prescription opioids, the regulators that oversee every one of those entities, approve prescription opioids, oversee every part of the process, they want the Court to ignore those.

Even the pharmacies are next direct point of contact as a distributor. Ignore those and put the blame for what the pharmacies do on the distributors. And then even among the distributors, they want the Court to find that any one of these distributors, among dozens of distributors that shipped to Huntington and Cabell, can be held responsible for everything.

In the case of McKesson if we look at the pills that McKesson distributed, the prescription opioids that it distributed, and we remove just the medications that it sent to the Federal Government, to the Veterans Administration, less than 10 percent of distribution into Huntington and Cabell County.

Mr. Farrell said all of the facets of this distribution chain have failed. They want the Court to ignore every one of them and say they can pick out one distributor, two distributors, three distributors and blame it all on them. The facts won't support that. The law doesn't support that.

The *Sharon Steel* case that the Court has no doubt focused on over briefing over the past several months

defines public nuisance, something that unlawfully operates to hurt and inconvenience.

That unlawfully, that unreasonableness, that's the conduct they're talking about that we'll be disputing. That hurt or inconvenience, that's the consequence they're talking about. There is harm.

That "operates to" language is the key to this case, causation. It's not enough that there be alleged misconduct. It's not enough that there be harm. They have to link them up and that's what the law tells us, including a case like the *Joint Commission* case from just last year from this court from one of Your Honor's callings.

There the party being sued was the Joint Commission that as Your Honor's already heard actually encouraged doctors to write more prescription opioids.

The Court in that case said, no, there's no causation. It's too attenuated. It's too remote. There are too many contributing causes.

In my time today I'll focus on two very distinct aspects of the opioid crisis: First, with the bulk of my time, prescription opioids, and then a little bit at the end heroin and illicit fentanyl, the horrible case of the opioid crisis today.

Let me start with prescription opioids and let me start with this volume point that it's already clear is central to

the plaintiffs' case. Their case depends on the suggestion that if they can just put up a chart with big numbers and say one for every man, woman, and child without looking at the science, they can show that data, they don't need to prove causation. They don't need to talk about our role in determining those levels or responding to the decisions of others who are determining those levels.

There are a lot of complicated legal and nuance factual responses to those arguments about volume, but I want to just start right away with the simplest one.

Distributors don't decide the volume. The volume of prescription opioids that goes out to patients is decided by doctors. If a doctor doesn't write a prescription, it sits on the shelf or it never even gets ordered by a pharmacy.

Doctors are the ones who determine the number of pills. That's what determines what pharmacies dispense. And what pharmacies dispense is what drives what manufacturers make and what distributors distribute.

Distributors are pulled along by the orders they get from the pharmacies. And what determines what the pharmacies dispense and what they order is doctors. McKesson doesn't set the level of distribution. It responds to it.

There is an important check on levels of prescription opioids that the Court has already heard about and will hear

about throughout the trial on the other end of the system and that's the DEA quota.

This is a 2019 Office of Inspector General report regarding how the DEA can exercise its quota responsibilities. And it defines the quota, the APQ, aggregate production quota, as the maximum amount of each basic class of Schedule I and Schedule II controlled substances the DEA administrator deems necessary.

Prescription opioids are unlike almost any other product in the country in that the Government limits the amount that can exist.

And what's critical in this language is the final highlighted language. The DEA sets that quota based on the estimated medical, scientific, research, and industrial needs of the United States or for lawful export.

So on one end, volume is determined by doctors. On the other end, it's capped by the DEA. Distributors sit in between and they don't set the volume.

In talking about prescription opioids, I'll talk first about the role of doctors, then the role of the DEA, and then McKesson.

It makes sense to start with doctors. Our common sense tells us we can't talk about prescription medications without talking about doctors. And the law codifies that principle.

This is the Code of Federal Regulations corresponding to the C.F.R. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner.

There's a corresponding responsibility with the pharmacist, no mention of distributors, but the responsibility for proper prescribing, dispensing of controlled substances is upon the prescribing practitioner.

So why is it that doctors began prescribing more prescription opioids? There was a movement in the medical community that the Court's already heard about going back to the '80s where doctors said, "We're not doing a good enough job to treat pain." This is Marcia Angell in the 1982 New England Journal of Medicine making that point. The treatment of severe pain in hospitalized patients is regularly and systematically inadequate. That's not for want of tools. It's generally agreed that most pain, no matter how severe, can be effectively relieved by narcotic analgesics.

That idea was picked up by institutions. This is the Joint Commission the Court has already heard about in 2001, the entity that was sued by the City of Huntington. This is that language the Court has heard about recognizing pain is a fifth vital sign, encouraging immediate assessment of pain, immediate treatment of pain.

Public health organizations and medical groups picked up that view. The DEA, the AMA, 2001 a dozen other organizations promoting pain relief and preventing abusive pain medications, critical balancing act. Again, this idea of under-treatment of pain is a serious problem in the United States.

And the answer for many patients, opioid analgesics when used as recommended by established pain management guidelines are the most effective way to treat their pain.

State medical boards around the country picked up on that idea, including here in West Virginia. This is the West Virginia Board of Medicine in 2005. "We recognize controlled substances, including opioid analgesics, may be essential." And they say exactly where; acute pain due to trauma, acute pain due to surgery, chronic pain whether due to cancer or non-cancer origins.

Three years later in 2008 the West Virginia Board of Medicine did something even more notable in this regard. They took this little book, "Responsible Opioid Prescribing, a Physician's Guide," and they sent it to every single doctor and every single physician's assistant in the state. And then they published a newsletter talking about how happy they were that they had done it, how it was the first undertaking of its kind by the board, and how 12 other states had done this too.

This publication that the West Virginia Board of Medicine, the licensing body for every single body, for every single doctor in West Virginia, literally the arbiter of the standard of care in West Virginia, that it sent to every single doctor, this is what it said.

"There is no debate among public health experts about the under-treatment of pain which has been recognized as a public health crisis for decades. The cost of under-treated pain in dollars is astronomical, but the cost in human suffering is immeasurable. Turning away from patients in pain simply is not an option."

Earlier in the publication, "Opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain whether it's cancer or non-cancer. Patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to patients."

This was 2008. That's exactly the point in time, if Your Honor thinks back to that curve, that Mr. Farrell referred to as a pill mill. It wasn't because of distribution. It was because of what doctors were being told by their own Board of Medicine and how distributors were responding to the decisions that doctors were making in the form of prescriptions.

At the start of this book, by the way, they contain a

little -- on the copyright page they contain a list of the sponsoring organizations. They have some companies on there including Purdue Pharma. They have some public health entities on there; the American Cancer Society, somewhat notably our Federal Government Substance Abuse Agency, the part of HHS responsible for substance abuse, the Substance Abuse and Mental Health Services Administration.

And right above the disclaimer, they say, "Care has been taken to confirm the accuracy of the information presented and to describe generally accepted practices." That was a medical decision that drove those levels, not the other way around.

In response to that guidance, doctors changed their prescribing practices. These are prescribing rates in Cabell County up through 2009. More recently as doctors have learned from the opioid crisis, they've gone back down.

The public health literature recognizes, the regulatory literature recognizes the role of doctors. In 2018 a publication from the DEA, factors contributing to the opioid problem in West Virginia, overprescribing of opioids, doctors in West Virginia prescribing at a higher rate according to this DEA publication.

It turns out that's true for many kinds of prescribing in West Virginia. They're higher than average. No mention of McKesson in this publication talking about factors

contributing to the opioid problem in West Virginia.

On those facts, the plaintiffs can't prove causation, and the case law recognizes that. In this *Joint Commission* case, the role of the physician was critical in preventing a finding of causation. No injury would occur unless the physician proceeded to unnecessarily prescribe treatments or if patients obtained the drugs through some other illegal means, no causation even to an entity that told those doctors to prescribe more.

The *Employer Teamsters* case also from this Court a little bit earlier, no causation where a vast array of intervening events, including the independent medical judgment of doctors, was what accounted for the harm.

Now, I want to touch very briefly on this. The Court's already heard about this from both of the other openings.

There are allegations of influence on doctors that doctors weren't just doing this for medical reasons, that they were influenced by companies to prescribe more opioids.

What's notable is that the discussions of that issue in the literature focus on manufacturers, not on distributors. And these plaintiffs themselves when they point to the marketing that they believe is important, it's manufacturer marketing. This is the City of Huntington in the *Joint Commission* case suing the Joint Commission.

And I think the Court's already seen this language.

They squarely point to the Joint Commission, the City of Huntington does, in this judicial admission. The Joint Commission teamed with Purdue, as well as other opioid manufacturers, to grossly misrepresent the addictive qualities of opioids with disastrous health consequences.

That's another complaint with one of these two, one of these two plaintiffs. This is the complaint in this case with both of these two plaintiffs, absolutely a judicial admission in this case.

Third amended complaint. They've had three times to say exactly what they mean to say against each of the defendants. Here's what they have to say about marketing, influencing doctors, and the causes of the opioid crisis.

It began with a corporate business plan. It started with a decision by Purdue and the Sackler defendants, the family that owns Purdue, to promote opioids deceptively and illegally.

Other manufacturers quickly joined. Through marketing that was as pervasive as it was deceptive, Marketing Defendants convinced healthcare providers both that the risks of long-term opioid use were overblown and that the benefits in reduced pain and improved function and quality of life were proven.

And this next language is the key quote. "The Marketing Defendants' scheme succeeded creating a public

health epidemic."

That's not our allegation of causation. That's the allegation of causation, the judicial admission from the plaintiffs in this case. The Marketing Defendants' scheme succeeded, creating, causing a public health epidemic. And they tell us exactly who those Marketing Defendants are: Purdue, other manufacturers listed by name, no mention of McKesson, no mention of Cardinal, no mention of ABDC.

And they back that up with close to 100 pages of detailed specific allegations of specific marketing, specific influence by manufacturers to support that claim that it was manufacturers who influenced doctors to prescribe more. Those are the plaintiffs' allegations.

That brings me to the role of the DEA. The DEA controls the entire controlled substances process, including registering all opioid prescribers. They have to be licensed by the state. But then to write prescriptions for prescription opioids, the DEA has to register them as well.

But in addition to registering and re-registering every three years all opioid prescribers, the DEA, as the Court's already heard, actually encouraged them to prescribe opioids.

The Court hasn't seen this language yet. It's striking. 2001 the DEA talking to doctors: "There are no limits. There are no limits on the quantity of controlled

substance dosage units under federal law or regulation that a practitioner may prescribe."

And they weren't simply telling doctors there are no limits when they said this. They were saying that to everyone in the healthcare system who has any role in satisfying doctor orders, including a distributor like McKesson. There are no limits for doctors.

If a company like McKesson in 2001 is asking what should prescribing levels be, this is the answer from the DEA. There are no limits for doctors.

They added to that statements, this in 2006 in the Federal Register. "The agency recognizes that nearly every prescription issued by a physician in the United States is for a legitimate medical purpose."

If you're wondering as a participant in the healthcare process if a prescription is legitimate, here's the DEA telling you almost every one is.

That's a view that we believe will be supported by the evidence in terms of doctors prescribing in good faith. It's certainly a view that the DEA holds right to this day.

This is the acting administrator of the DEA testifying before Congress in 2018. I go back to the fact that I look at the vast majority of doctors. 99.99 percent are all trying to do right by their patients.

That testimony is decisive in its own way, and it's

decisive in this fashion. The allegations that the plaintiffs are making repeatedly is based on the statute that speaks to the maintenance of effective controls against diversion.

But baked into that statute that talks about preventing diversion, preventing the medications from going where they're not supposed to go, baked into that statute is the concept that distributors don't second guess legitimate medical judgment.

It's maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels. And it shows how gaping the disconnect is between the role of a distributor and the harm they're trying to pay on distributors here to see that and to know that the DEA was telling distributors almost every prescription is legitimate. Almost every doctor is legitimate. There are no limits on how much a doctor can prescribe.

That was confirmed by the fact that the DEA had full visibility into the volume of distribution from distributors.

The Court's already heard about the ARCOS database. This is a presentation that the DEA did of some of this data in 2011 where they were showing exactly what kind of things they could do with this database. And they were very clear.

They could look state by state with this database at any point in time. They could look county by county.

This, of course, in this public presentation they gave is a map of North Carolina. They could do the same thing for West Virginia and make judgments about whether a county was average, below average, above average, whether pharmacies were above average or not.

They had full visibility, full transparency into exactly the volumes that were being distributed in response to doctors writing prescriptions. And they didn't just have full visibility. They had the power to regulate how much would be made and then dispensed and then prescribed through their quota.

This is what the quota looks like for only Oxycontin as reported in this OIG report that I mentioned right through the height of the opioid crisis.

And that's not simply allowing more prescription opioids to be used. That's telling the country and entities involved in the healthcare system what's appropriate in terms of prescription opioids because what the DEA is supposed to look at in setting the quota is the estimated medical, scientific research and industrial needs of the United States.

If a company like McKesson is looking at that kind of chart that the Court was shown and sees raising levels and

wants to know is that appropriate in terms of what's medically, scientifically appropriate, the DEA is saying, yes, we need more prescription opioids every year, even up to after the point when McKesson's started to go down.

Only recently the DEA has started to lower the quota. And in hindsight, the DEA has been criticized by the Government for not doing a better job with the quota. This report makes that point. The Court heard reference to a report right here from West Virginia making that point.

The Attorney General went out just last year, obtained documents from the DEA to look at how they did their quota work and concluded with legal authority and resources to take responsibility for this issue, diversion, the DEA did not fulfill its duty to act as a robust gatekeeper when setting APQs, aggregate production quotas. The DEA was asleep at the switch when it came to setting APQs.

That brings me to McKesson's role. And I'll start by talking about the purpose of a company like McKesson and then I'll talk about those responsibilities.

In terms of the purpose of a company like McKesson, it's to supply medicine, to supply medicine that our society through the FDA and in some instances through the DEA has said this has value. This should be available for patients with a prescription. To this day, that includes prescription opioids.

This is a letter from the American Medical Association just this past summer. Even today, opioids have their appropriate place as an option for treatment of acute pain, palliative and end of life pain management, cancer pain, and some chronic pain patients.

The DEA has consistently recognized the importance of ensuring that companies like McKesson do their jobs and make sure prescription opioids are available when needed in pharmacies.

This is congressional testimony from Mr. Rannazzisi who the Court has already heard about. He will be presented during the plaintiffs' case as a fact witness in this case. He's a paid plaintiffs' expert for other plaintiffs suing distributors. While he was still at the DEA, this is what he said about this key importance to a company like McKesson.

"It is vital that an adequate and uninterrupted supply of pharmaceutical controlled substances be available for effective patient care."

DEA recognized it is a public health concern. It is a public health concern when pharmacies can't dispense legitimate controlled substances to patients. It's a public health concern when a company like McKesson doesn't do its job. And you see that, I think, most vividly in the customers that McKesson has.

McKesson has two buckets of customers in Huntington and Cabell County. The first bucket is hospitals and health clinics. Many of these are probably familiar to the Court.

I want to focus on one of those in particular, the V.A., the Federal Government. If there's any entity that should be beyond reproach in terms of sending prescription opioids to them, it should be the Federal Government, the entity that wrote the CSA, the Controlled Substances Act, administers it, implemented it, oversees it, and not just any branch of the Federal Government but the branch of the federal Government responsible for caring for service men and service women, whether they're coming back from Iraq and Afghanistan with pain needs or whether they're retired with conditions like cancer that carry pain needs.

The V.A. -- a process that's overseen literally by the Federal Government to make sure that prescription opioids in that setting are appropriate.

The V.A. is critical in this case for McKesson because the vast majority of McKesson's shipments to Huntington and Cabell went to the V.A. You count the numbers differently according to which medications you include or don't include, but by what we think is the best calculation, 76.8 percent of McKesson's shipments to Huntington and Cabell were to the Federal Government caring for service men and service women and retired service men and service women.

McKesson's other customers are traditional pharmacies, chain pharmacies, independent pharmacies, some of which the Court is probably familiar with. And if you combine those with the hospitals and health clinics I just spoke about, that's the universe of McKesson customers in Huntington and Cabell.

Now, if I come back to this V.A. point and I take the V.A. out of this group, if we exclude shipments to the V.A., which is something that even two of the plaintiffs' experts did when they were performing analyses of allegedly suspicious or questionable orders, they excluded the V.A. too along with some other hospitals. If I just take the V.A. out of, out of Huntington/Cabell numbers, this is McKesson's market share, 6.6 percent excluding the V.A.

And in much the same way as the absence of doctors and the absence of manufacturers and the absence of regulators and the absence of pharmacies tells us something about this case, this statistic too tells us something about this case.

The argument that a distributor with its narrow role that's less than one in ten shipments to Huntington and Cabell can be held responsible for the whole opioid crisis, that argument tells us this isn't about causation. It's not about causation as to McKesson. It's not about causation as to Cardinal. It's not about causation as to ABDC.

Let me turn now to McKesson's responsibilities. And

before I do, I want to talk about this idea of diversion. There are many different types of diversion and it will be important to present -- for us to present evidence on that during trial.

This is the distribution chain that I showed the Court earlier. Frankly, I believe the very best distribution chain the Court's seen all day.

Diversion can occur at any stage of this process. There will be no serious evidence that diversion occurred while McKesson had prescription opioids.

But it can also occur after a patient gets a medicine and a non-patient ends up with that medicine. It can occur when McKesson does everything it is supposed to do, a legitimate prescription gets dispensed, and a thing gets diverted. It gets stolen from a patient. It gets sold. It gets given away. That's critical in evaluating the opioid crisis, that form of diversion that a company like McKesson has nothing to do with.

It's critical because healthcare agencies, including this publication from the CDC, tell us that more than half of diversion that occurs is that form of diversion that McKesson has nothing to do with.

In this publication, three out of four people who misuse prescription painkillers use drugs prescribed to someone else. Most of the diversion that occurs occurs

after a distributor has done what it's supposed to do.

Your Honor has heard reference made to diversion from pharmacies. And there will be a lot of evidence presented in terms of diversion from pharmacies. There was no -- in the discussion about McKesson earlier today there was no mention of any McKesson pharmacies where diversion occurred, but I suspect we'll hear that at trial.

I want to highlight a very notorious diverting pharmacy in Cabell County, A-Plus Care Pharmacy. This is the 2014 Huntington police report. This was one of their larger investigations, the A-Plus Care Pharmacy investigation.

This operation shut down a major source of supply for pharmaceutical diversion to the Tri-State area and beyond. Why didn't Your Honor hear about it? None of the defendants supplied this pharmacy. There's again a disconnect between the conduct they're alleging and the harm they're alleging.

In terms of McKesson's responsibilities, one of its most important responsibilities has actually been proven up by the plaintiffs in their opening argument. And that's this reporting of ARCOS data that the DEA then uses to analyze potential diversion in pharmacies.

I showed the Court these slides earlier. I want to show the Court one more slide showing how the DEA can use it to determine if a pharmacy was outside the norm.

In the plaintiffs' presentation this morning there was

talk about transparency. I think there was a picture of an iceberg with a little biddy bit above and a lot below.

There was full transparency into McKesson's distribution as to the DEA. They gave the DEA all of their data. The DEA had full transparency into their data. And we know from the very charts that were shown this morning based on DEA data that the DEA was able to use that data. They had it not just for McKesson, but for every distributor.

The only place where there's a lack of transparency was the DEA refused to share that data that they received from other distributors with individual distributors. It took an act of Congress a few years ago to require them to share their ARCOS data.

Mr. Rannazzisi, who the Court will hear from, acknowledged that fact. Registrants, that's distributors, have requested access to ARCOS and may have been declined, yes.

So the transparency was not with McKesson. McKesson told the DEA, as required, "Here are all of our shipments."

In addition to that, the Court will hear evidence over the course of the trial about diligence steps that McKesson has undertaken over time and grown over time in response to the opioid crisis and in response to guidance from the DEA.

This is a presentation McKesson gave to the DEA in

2008. The Court will remember that there was discussion about a McKesson settlement in 2008. In response to that, it was one of many settlements the DEA entered into with companies.

In response to that, McKesson went to the DEA and said, "This is what we're going to do. Tell us if this is okay or if you have any changes."

They gave a detailed presentation. We're going to have thresholds for every single customer. We're going to investigate every single one of our existing customers to make sure we get the thresholds right and that we're comfortable dealing with them. We're going to investigate new customers who come on with us, including assessing their history. We're going to block orders that go over our thresholds. We're going to review and escalate if they do go over our thresholds.

And this is important for the later settlement. McKesson understood the DEA to be saying, "We want fewer suspicious orders." So they said McKesson is prepared to stop excessive purchases reporting to a local field office.

This continued over time. There was a dichotomy presented this morning. I think the suggestion was that up until 2012, companies said, "We want to do right. We want to try to address the DEA." And then in 2012 they started fighting with the DEA.

And that dichotomy is simply not true when held up against McKesson's programs. Over time, McKesson continually improved its programs, including major improvements in 2013 and 2014.

This is language of the settlement agreement that the Court was shown from 2008. I want to highlight one passage not shown.

McKesson asked the DEA to commit to reviewing specific McKesson distribution centers, and the DEA agreed. "We shall conduct reviews of the functionalities of McKesson's diversion compliance program. The standard for passing, maintaining effective controls against diversion, detecting and reporting suspicious orders, meaningfully investigating new or existing customers."

McKesson tried to work with the DEA, including this term in the settlement agreement to give the DEA what it believed it was looking for. In the face of that, the plaintiffs can't link their criticisms to any harm.

The *Sharon Steel* standard requires that. They must operate to cause the harm. I'll touch very quickly on the two principal conduct allegations that the plaintiffs make against McKesson and against each distributor.

The first is that before 2008, companies would report suspicious orders to the DEA, but they would send them out. They would not block them. The reason they did that is

because they expected if the DEA had concerns when they got those reports, they'd tell the company or they'd tell the pharmacy.

That was known by the DEA and it was approved by the DEA. And that's documented in a Federal Court decision from a few years after companies started blocking. This is Eastern District of Michigan 2012. It was standard practice in the industry to file suspicious order reports while continuing to ship products, and that practice had been approved by the DEA.

The Government offered testimony that the DEA sought to expand drug wholesaler's obligations by changing policy in 2006 and 2007. That's what started companies blocking in 2008, although there was never a change to the regulations.

This case is not -- this Eastern District of Michigan case is not abstract to the case before the Court. It has a specific connection to the case before the Court.

When this Court said the Government offered testimony, that testimony included testimony from the single DEA expert witness that the plaintiffs intend to introduce here, James Rafalski.

When Mr. Rafalski was acting as a public servant, building the expertise that the plaintiffs claim now allows him to testify as an expert before Your Honor, he was testifying in Federal Court that blocking was not required

before 2008, and that it was only in 2006 and 2007 that things started to change. That criticism can't be linked to harm.

Their second criticism Your Honor has already heard referenced to not reporting more suspicious orders in the case of McKesson, that's going to focus on 2008 to 2013.

What the plaintiffs didn't tell you about that is during that time period, McKesson was blocking orders. So it wasn't reporting suspicious orders as much, but it was blocking many, many more orders.

And Mr. Rannazzisi conceded the basic principle of physics. If you don't ship an order, they don't have the drug, so the drug can't be diverted. They can't link their criticism to actual harm in terms of diversion.

That OIG report tells us the same thing. The OIG looked at what the DEA did with suspicious orders. They said the field division staff, the people who investigate pharmacies, they didn't even get access to the source database or the suspicious order reporting system database until 2017.

What were they looking at? They were looking at ARCOS, the data that McKesson indisputably produced. They had what they needed. They can't -- the plaintiffs can't link suspicious orders to any form of harm. And the real world proves that out.

For McKesson's warehouse, distribution center to ship prescription opioids into the State of West Virginia, it has to be approved by the State of West Virginia. The state applies specific standards. They must comply with federal regulations. They have to have maintenance of effective controls against diversion.

This is the most recent approval for the distribution center that principally ships to West Virginia for McKesson from 2020. In the time just since 2014, 150 approvals of McKesson distribution centers from West Virginia, even more if we went back further in time, 62 just since the plaintiffs filed this lawsuit.

That's prescription opioids. I'll use my brief time remaining to address heroin and illicit fentanyl.

As I mentioned at the beginning, this is the face of the opioid crisis today. This again is the American Medical Association from last summer. The nation no longer has a prescription opioid driven epidemic.

However, we are now facing an unprecedented multi-factorial, multi-cause, much more dangerous overdose and drug epidemic driven by heroin, illicitly manufactured fentanyl, fentanyl analogs, and stimulants. The horrifying data bears that out. This is data on overdose rates in Huntington, horrifying data. That's prescription opioids. That's illegal heroin and fentanyl.

So how is it that the plaintiffs seek to hold McKesson responsible for products it never touched that are trafficked by criminals? It's that gateway theory the Court's already heard about.

This idea -- I think the way they want to present it is this idea that no one today would be using heroin but for the fact that they got a single opioid prescription for a root canal or a sprained ankle. I suspect the Court's life experience already tells the Court the affliction, the scourge of addiction is more complicated than that. And that's what the science will show.

This is an example of one of the studies that the plaintiffs rely on, the SAMHSA study from 2013. And what it did was it looked at people who started using heroin in the past year and it asks a simple question: Did they abuse prescription opioids before?

They found a really large number, up to 80 percent. That number's come down in recent years, but it's a really large number. What's critical about that is that's misuse of prescription opioids. There's no similar data for legitimate use of prescription opioids. But it's, nevertheless, a very high number.

But what these authors did next is they said, "Well, what about other drugs?" How many of these people -- we know 79.8 abuse prescription opiates. How many of them

abuse cocaine and marijuana and hallucinogens and other illegal drugs?

And this is what they found. Nearly every one. And that's what the science will say. It's complicated. There are all kinds of factors that drive the affliction of addiction; alcohol abuse, family history, psychiatric history, socioeconomic factors.

The Court will see again and again that when public health officials and scientists look at this question, this is the National Institutes on Drug Abuse, they say that data that we just looked at is really strong, but we can't come to a conclusion about causation. It's complicated.

Now, that's the science response to the gateway theory. I want to give the Court a much more basic factual legal response. And that's this. The Court might believe the gateway theory advocated by plaintiffs' experts in its fullest form. The Court might reject it. It might come somewhere in between.

Regardless, they still can't prove causation for this reason. I showed the Court the distribution chain for legal prescription opioids. This is the distribution chain for illegal heroin and illegal fentanyl.

Drug cartels, El Chapo, make the drugs in Mexico for heroin, in China for fentanyl. Drug traffickers violate our nation's sovereignty crossing our borders bringing it into

our communities. Street gangs prey on vulnerable individuals and sell drugs.

These are the people who are taking the actions that cause heroin and illicit fentanyl harm. These are the people who are making the decisions that lead to that harm. And both the science and law enforcement will tell us that again and again.

This is that review article from the National Institute on Drug Abuse. Heroin market forces, including increased accessibility, reduced price, and high purity of heroin appear to be major drivers of the recent increases. Those are actions taken and decisions made by criminals that a company like McKesson regulated and licensed by the Government has nothing to do with.

Law enforcement, same point. Large increases in poppy cultivation and heroin production in Mexico, a steady stream of high purity, low-cost heroin to markets throughout the United States.

We can look closer to home. Huntington. Huntington is a destination city known and utilized by Detroit violent gang members and narcotics traffickers to establish heroin distribution points in other parts of the Tri-State region.

That brings me back to the law, the *Joint Commission* case recognizing that even the criminal actors, the people diverting legal prescription opioids cuts off causation, let

alone criminals trafficking an entirely different product.

No causation with plaintiffs' claims rely on various criminal actions of third parties. Defendants' actions are too attenuated and influenced by too many intervening causes, including the criminal actions of third parties to stand as the proximate cause of plaintiffs' injuries.

And that brings me back to where I began. I'll close with where I began with causation, that essential principle of law, that key element of tort law that provides a guarantee of fairness and reasonableness and proportionality and justice, that requirement that there be a straight through line from what they're saying someone did wrong to the harm they're alleging.

There is no magic that allows someone to take a complicated public health crisis like the opioid crisis and just by saying public nuisance or joint and several liability wipe away that foundational principle of causation. But that's just what their claims depend on.

Their claims depend on them criticizing conduct five years ago, 10 years ago, 20 years ago and saying that through that criticism of that conduct related to legal prescription opioids, and just on the distribution of them to pharmacies, through that criticism, they can skip over causation and assign responsibility in 2021 all the way through 2035 for illegal heroin and illicit fentanyl,

products McKesson never touched, trafficked by sophisticated criminals that McKesson has nothing to do with.

There's no magic that allows them to get rid of causation in that way. They can't wipe aware fairness. They can't wipe away causation and the fairness that it encompasses even if we all agree that there is a public health crisis involving illegal heroin and fentanyl. The law says causation still matters. The law stands in the way of their claims. The facts won't support their claims. And we look forward to the opportunity to present that through this trial.

Thank you, Your Honor.

THE COURT: Thank you, Mr. Schmidt.

We'll start the evidence at 9:00 tomorrow morning. And I'm assuming there's nothing we need to do this afternoon.

All right, see everybody in the morning.

(Trial recessed at 4:55 p.m.)

CERTIFICATION:

I, Ayme A. Cochran, Official Court Reporter, and I, Lisa A. Cook, Official Court Reporter, certify that the foregoing is a correct transcript from the record of proceedings in the matter of The City of Huntington, et al., Plaintiffs vs. AmerisourceBergen Drug Corporation, et al., Defendants, Civil Action No. 3:17-cv-01362 and Civil Action No. 3:17-cv-01665, as reported on May 3, 2021.

S\Ayme A. Cochran
Reporter

s\Lisa A. Cook
Reporter

May 3, 2021
Date